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Civil Liability Challenges for the Law and Neural Interface Devices: Reconceptualising the Law

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Abstract

Neural interface devices are artificial devices that are controlled by the human mind. Neural interface systems encompass sophisticated technology that enables integration of machine with the human brain and body. The complexity of the brain and neural system is so great that full understanding of how these work is still being discovered through neuroscientific research. Interfacing with the human brain and neural system is far from perfect so the ways in which they work and the limitations of neural interface devices must be recognised when a dispute comes before a court of law.

The research hypothesis tested in this thesis is that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action. Complexity will arise because of the existence of the neural interface device and what might be regarded as a merging of mind and machine. This will make it difficult to determine factual causation and as a result, the law will need to adapt to these circumstances. Thomas Kuhn's concept of revolutionary science, involving paradigm shift, is applied to determine this hypothesis.

While doctrinal methodology is applied in the analysis of the law, policy considerations that will impact on the judicial decision making and legislative action are also discussed. Delphi Method research has been undertaken to obtain the insight of legal experts regarding the legal issues that will arise in the context of civil disputes and how the current law will address these issues. The information upon which the participants in the Delphi Method research based their responses purposely excluded malfunction of the neural interface device. While malfunction of the device is considered when analysis of manufacturer liability is undertaken, the law will have most difficulty determining liability when the device does not malfunction.

In the analysis of the legal issues, scenarios have been introduced to better assess the application of the law and identify the difficulties that will require re-evaluation and adaptation of the law. While the facts that arise in disputes differ, identification of the difficulties the current law will have in resolving a dispute based on the scenarios presented in this thesis will provide insight for future civil proceedings where the person with a neural interface device is involved. Throughout this thesis, the person with the neural interface device is regarded as a defendant in a civil proceeding. The issues involving neural interface devices

are multifactorial, so while neuroscientist and engineers develop neural interface devices, lawyers, academics and politicians must consider the ethical, legal and social frameworks within which innovation can exist and thrive. This thesis concludes with recommendations, based on the legal issues identified and analysed, to assist the judiciary, the legislature and the legal profession with this new area of technological advancement.

The challenges that the melding of mind and machine through neural interface present at law are analysed throughout this thesis. This thesis seeks to provide a substantial contribution to the legal literature that is both innovative and pioneering. This new, developing field of inquiry provides the opportunity for ground breaking advances in legal analysis of the existing legal frameworks that, in particular circumstances, will require re-evaluation and adaptation.

Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

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Publications included in this thesis

No publications included.

Submitted manuscripts included in this thesis

No manuscripts submitted for publication.

Other publications during candidature

Peer-reviewed papers

Scott Kiel-Chisholm and John Devereux, 'The ghost in the machine: Legal challenges of neural interface devices' (2015) 23(1) *Tort Law Review* 32.

Other publications

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Research Involving Human or Animal Subjects

Ethics approval was obtained from the TC Beirne School of Law Research Ethics Sub-Committee for the Delphi Method Research. A copy of the ethics approval email is Appendix A.

Ethics approval was obtained from the TC Beirne School of Law Research Ethics Sub-Committee for the meeting with representatives of DEKA Research and Development Corporation. A copy of the ethics approval email is Appendix B.

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List of Abbreviations used in the thesis

Abbreviation	Meaning
2D	2 dimensional
3D	3 dimensional
ACL	*Australian Consumer Law* that is Schedule 2 of the *Competition and Consumer Act 2010* (Cth)
AIMD	Active implantable medical device
ALS	Amyotrophic lateral sclerosis also known as Lou Gehrig's disease
ARGMD	Australian Regulatory Guidelines for Medical Devices
ARTG	Australian Register of Therapeutic Goods
BCI	Brain-computer interface
BMI	Brain-machine interface
BNCI	Brain-neural-computer interface.
CAI	Centre for Advanced Imaging
CCA	*Competition and Consumer Act 2010* (Cth)
CLANSW	*Civil Liability Act 2002* (NSW)
CLAQ	*Civil Liability Act 2003* (Qld)
CLAS	*Civil Liability Act 1936* (SA)
CLAT	*Civil Liability Act 2002* (Tas)
CLAWA	*Civil Liability Act 2002* (WA)
CLWACT	*Civil Law (Wrongs) Act* 2002 (ACT)
DARPA	Defense Advanced Research Projects Agency
DBS	Deep brain stimulation
DEKA Arm	DEKA Arm, now called the LUKE arm
ECoG	Electrocorticography
EEG	Electroencephalogram
EMG	Electromyograph
FDA	Food and Drug Administration
FES	Functional electrical stimulation
fMRI	Functional magnetic resonance imaging
IMU	Inertial measurement units
IVD	In vitro diagnostic
LFPs	Local field potentials

LUKE	Life Under Kinetic Evolution
MIT	Massachusetts Institute of Technology
MRI	Magnetic Resonance Imaging
NESS	Necessary Element for the Sufficiency of a Subset of the facts
NID	Neural interface device
NIF	National Imaging Facility
NIH	National Institutes of Health
NIS	Neural interface system
NMP	Neuromotor prostheses
ODA	Office of Devices Authorisation in the Therapeutic Goods Administration
OPR	Office of Product Review in the Therapeutic Goods Administration
PET	Positron emission tomography
QEEG	Qualitative electroencephalogram
RFID	Radio Frequency Identification Device
SMR	Sensorimotor-rhythm or μ-rhythm
SNR	Signal-to-noise ration
SPECT	Single Photon Emission Computerised Tomography
TGA	Therapeutic Goods Administration in Australia
WAVIC	*Wrongs Act 1958* (Vic)

I CHAPTER 1 INTRODUCTION AND OVERVIEW

A *Abstract*

Neural interface devices are artificial devices that are controlled by the human mind. The research hypothesis tested in this thesis is that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action. Complexity will arise because of the existence of the neural interface device and what might be regarded as a merging of mind and machine. This will make it difficult to determine factual causation and as a result, 'the law, marching with medicine but in the rear and limping a little',[1] will need to adapt to these circumstances. Thomas Kuhn's concept of revolutionary science,[2] involving paradigm shift, is applied to determine this hypothesis. While doctrinal methodology is applied in the analysis of the law, policy considerations that will impact on judicial decision making and legislative action are also discussed. Delphi Method research has been undertaken to obtain the insight of legal experts regarding the legal issues that will arise in the context of civil disputes and how the current law will address these issues. The information upon which the participants in the Delphi Method research based their responses purposely excluded malfunction of the neural interface device as the law will have most difficulty determining liability when the device does not malfunction.

In the analysis of the legal issues, scenarios have been introduced to better assess the application of the law and identify the difficulties that will require re-evaluation and adaptation of the law. While the facts that arise in disputes differ, identification of the difficulties the current law will have in resolving a dispute based on the scenarios presented in this thesis will provide insight for future civil proceedings where the person with a neural interface device is involved. Throughout this thesis, the person with the neural interface device is regarded as a defendant in a civil proceeding. The issues involving neural interface devices are multifactorial, so while neuroscientist and engineers develop neural interface devices, lawyers, academics and politicians must consider the ethical, legal and social frameworks within which innovation can exist and thrive. This thesis concludes with recommendations,

[1] *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383, 395 (Windeyer J).

[2] Thomas S Kuhn, *The Structure of Scientific Revolutions*, (The University of Chicago Press, 2nd ed, 1970).

based on the legal issues identified and analysed, to assist the judiciary, the legislature and the legal profession with this new area of technological advancement.

B *Introduction*

The use of prosthetics is not a new medical development, however, the ability of the human brain to instruct and control these devices is fast becoming a reality. These new mind-controlled devices are called neural interface devices. For the purposes of this thesis, the words 'mind' and 'brain' are interchangeable. This is not intended to diminish the different factual definitions of both but to incorporate terms that have been reinforced in academic authorship on the topic of neural interface.[3] With all innovation comes new opportunities, new accomplishments and new challenges. For neural interface devices, the degree to which the devices are becoming incorporated into the human being may be to the extent that melding of mind and machine occurs. As this integration becomes more prevalent, the law will experience difficulty in establishing where liability for injury, damage or loss to the property or person of another should lie. Determination of whether liability should be placed solely on the person with the neural interface device, solely on the manufacturer of the neural interface device or shared between the two, will be a challenge within the context of the facts of each case. The thesis examines the issues the law will experience as the merging of mind and machine becomes an integral part of civil proceedings. For example, causation in a negligence action will need to be determined, so the role of both the neural interface device and the person's brain will be important.

The human senses of sight, sound and touch play an integral role in facilitating the interaction between people and electronic devices such as computers, scanners and multifarious mobile devices.[4] 'But remove those senses from the equation, and electronic devices can become our eyes and ears and even our arms and legs, taking in the world around us and interacting with it through man-made software and hardware'.[5] Dr Jens

[3] For example, see Ray Kurzweil, 'The Coming Merging of Mind and Machine' (2009) *Scientific American* (online) <https://www.scientificamerican.com/article/merging-of-mind-and-machine/>; Maartje Schermer, 'The Mind and the Machine. On the Conceptual and Moral Implications of Brain-Machine Interaction' (2009) 3 (3) *NanoEthics*, 217; Raya Bidshahri, *How Will Merging Minds and Machines Change Our Conscious Experience?* (12 April 2018) SingularityHub< https://singularityhub.com/2018/04/12/how-will-merging-minds-and-machines-change-our-conscious-experience/>; Lara Fernandez, *How brain–computer interface is merging mind and machine* (2017) Deakin University <https://this.deakin.edu.au/innovation/is-netflix-shrinking-australias-film-and-television-industry>.

[4] Jens Clausen, 'Man, machine and in between' 457 (2009) *Nature* 1080.

[5] Ibid.

Clausen assures us that this has already happened[6] and according to Emory University Neuroscience Professor, Dr Michael Crutcher, 'anything can happen' in this innovative field of neurology.[7]

Neurosurgeon, Eric Leuthardt, said 'I saw neuroprosthetics in the very early, seminal stages and I thought, this is it. This is the future.'[8]

> Leuthardt was not alone. The field was already thick with speculation that scientists could craft a neural augment for people with paralysis. In 1998, an Irish researcher named Philip Kennedy demonstrated that he could endow a man paralyzed from the neck down with a rudimentary control of a computer program. One year later, the German researcher, Niels Birbaumer, used EEG to enable similarly impaired patients to control basic word processing software, and by 2001 one of the field's titans, a neuroscientist named John Donoghue, cofounded Cyberkinetics, a neurotechnology company aimed at developing commercial brain-computer interfaces.[9]

This field of neurology is different from the advances in robotics where researchers strive to make robots more like human beings. In 2011, Professor of Robotics at Carnegie Mellon University in Pittsburgh USA, Dr Reid Simmons, stated that 'in five or ten years robots will routinely be functioning in human environments'.[10] Commonly known as androids, these new generation robots are designed 'to function not as programmed industrial machines but as increasingly autonomous agents capable of taking on roles in our homes, schools, and offices previously carried out only by humans'.[11]

In contrast, neural interface systems include devices that sense brain signals, a signal processor or decoder and a device to effect action, in clinical terms - an 'assistive technology'.[12] For the purposes of this thesis, a neural interface device composes of a neural sensor, decoder and assistive device, as shown in Figure 1.1 below. Neural interface

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[6] Ibid.

[7] Anne Hammock, 'The future of brain-controlled devices' *CNNTech* (4 January 2010) <http://edition.cnn.com/2009/TECH/12/30/brain.controlled.computers/index.html>.

[8] Malcolm Gay, *The Brain Electric* (Text Publishing, 2015) 15.

[9] Ibid 15-16. 'EEG' means Electroencephalogram.

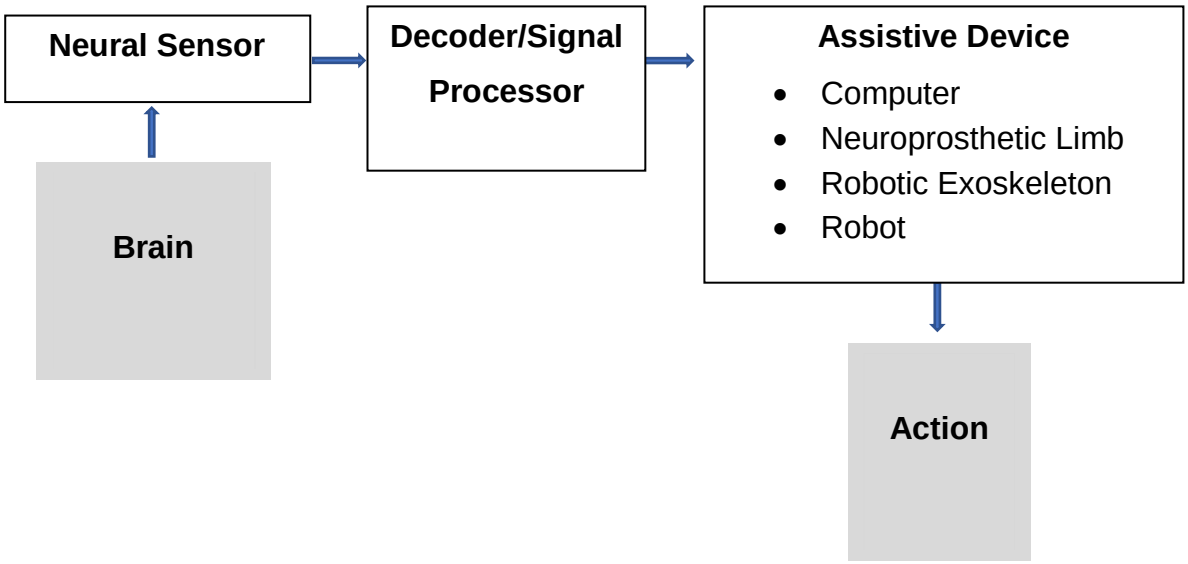
[10] Chris Carroll, 'Us. And them' (2011) 222(8) *National Geographic* 66, 72.

[11] Ibid.

[12] John P Donoghue, 'Bridging the Brain to the World: A Perspective on Neural Interface Systems' (2008) 60(3) *Neuron* 511.

devices incorporate technology that sense, record and interpret neural activity and then send a command to an assistive device such as a computer, neuroprosthetic device, exoskeleton which may be attached or to a robot that is separate from the person but is connected by thought alone.

Figure 1.1. Design of a Neural Interface Device[13]



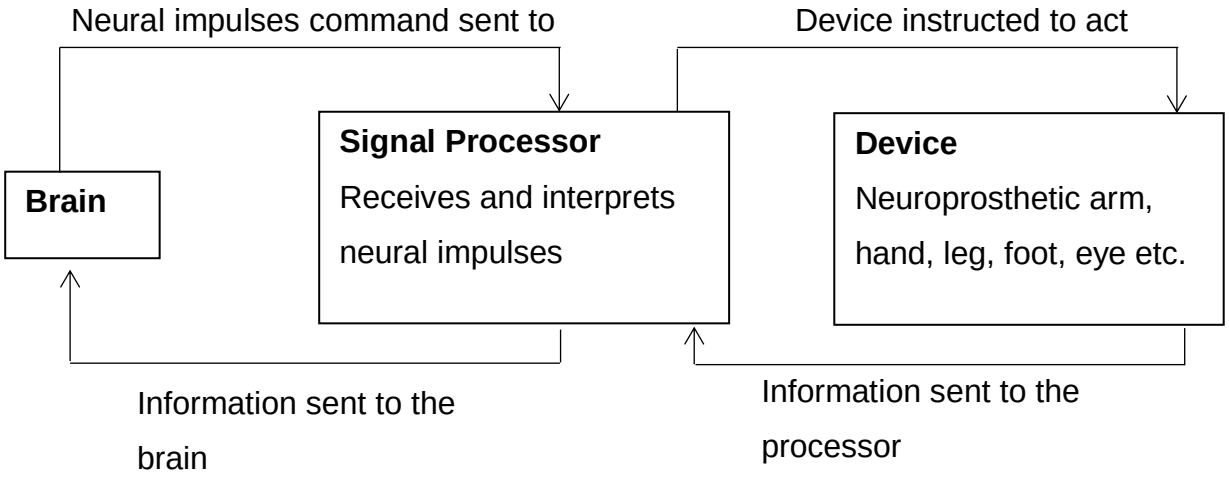
Source: Adapted from John P Donoghue, 'Bridging the Brain to the World: A Perspective on Neural Interface Systems' (2008) 60(3) *Neuron* 511, 512.

This innovative technology is being achieved through brain–computer interface research and development. The assistive devices connect with the brain through the nervous system, and operate on neural impulses alone, in the absence of muscular or other physical movements of the body.[14] For the purposes of this thesis, the neural interface device integration with the human body is such that communication flows between the brain and neural processor that instructs the assistive device. However, the assistive device also communicates with the brain by sending information through the neural processor or decoder, as outlined in Figure 1.2 and discussed in detail in chapter 3.

[13] Adapted from Donoghue, above n 12, 512.

[14] Alejandra Martins and Paul Rincon, 'Paraplegic in robotic suit kicks off World Cup' *BBC News* (online), 12 June 2014 <http://www.bbc.com/news/science-environment-27812218>; Bridie Smith, 'Human trials for Australian-made bionic spine to start next year' *The Sydney Morning Herald* (online), 9 February 2016 <http://www.smh.com.au/technology/sci-tech/human-trials-for-australianmade-bionic-spine-to-start-next-year-20160202-gmjqdj.html>.

Figure 1.2 Neural Interface System



This research examines the civil liability of persons with neural interface devices who allegedly cause property damage or personal injury to another. The ability of the law to address this currently unique situation will have a fundamental impact on all of those concerned with the incident, including society at large. The current law will have difficulty resolving the civil liability issues that will arise in these circumstances as the integration of neural interface devices with the human mind moves well beyond the current law. Where difficulties arise, recommendations for both common law and legislation may assist in providing a legal framework in which these innovative devices can be used safely for the benefit of those in need.

The thesis is ground breaking as the law has yet to address the civil liability of a person with a neural interface device. This is evidenced by the lack of cases and legal literature in the area. The legal principles of negligence provide a platform on which to build credible legal analysis of liability of individuals with, and manufacturers of, neural interface devices. These legal principles will be applied to the current environment in which neural interface devices exist. Chapters 4 and 5 provide analysis of negligence and manufacturer liability, respectively. In fact, there are a myriad of legal issues that will arise in this field. While extensive analysis of these issues is beyond the scope of this thesis, chapters 1 and 6 introduce some of these. Chapter 3 provides the results of Delphi Method research that involved engagement with legal experts regarding legal issues in this field.

The contribution to legal literature will be substantial, innovative and pioneering. This new, developing field provides the opportunity for ground breaking advances in legal analysis.

C *This Thesis*

1 *The Hypothesis*

The research hypothesis analysed in this thesis is that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action. No assumption is made that the hypothesis is correct and the research was undertaken to determine the validity of the hypothesis.

2 *The Chosen Theory for Hypothesis Determination*

Determination of the research hypothesis requires a test that recognises deviations from the norm. For adequate resolution of civil disputes there must be the application of both procedural and substantive law to arrive at a determination. The doctrine of precedent requires the application of authority to the case at hand, ensuring the court's decision is consistent with the authority and avoiding conflict with existing law. In this way, a paradigm, or framework through which knowledge is filtered, develops.[15] The common law evolves as matters come before the courts that challenge the application of the current law or make it difficult for the current law to be as strictly applied. This legal evolution was evident in the case of *Donoghue v Stevenson ('Donoghue')*.[16]. In *Donoghue*, Ms May Donoghue drank from a bottle of ginger beer purchased by a friend of hers and manufactured by Mr David Stevenson. The bottle, unbeknownst to Ms Donoghue, had a snail in it. Ms Donoghue subsequently became ill and took legal action against Mr Stevenson. At that time, the courts looked to the existence of a contract when determining if there was a relationship upon which a duty of care would arise. There was no contract between Ms Donoghue and Mr Stevenson which presented the court with the difficulty of providing a remedy based on the existing law.

In 1932 there was no *general* principle of duty of care. However, in the opening of his Honour's judgment, Lord Thankerton stated, 'The action is based on negligence.'[17]

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[15] Patricia Leavy, *Research Design: Quantitative, Qualitative, Mixed Methods, Arts-Based, and Community-Based Participatory Research Approaches* (Guilford Publications, 2017) 11.

[16] [1932] AC 562.

[17] *Donoghue v Stevenson* [1932] AC 562, 601.

After summarising Ms Donoghue's case, Lord Thankerton stated:

> There can be no doubt, in my opinion, that equally in the law of Scotland and of England it lies upon the party claiming redress in such a case to show that there was some relation of duty between her and the defender which required the defender to exercise due and reasonable care for her safety. It is not at all necessary that there should be any direct contract between them, because the action is not based upon contract, but upon negligence; but it is necessary for the pursuer in such an action to show there was a duty owed to her by the defender, because a man cannot be charged with negligence if he has no obligation to exercise diligence: *Kemp & Dougall v. Danakil Coal Co.* 1909 SC 1314, 1319 , per Lord Kinnear; see also *Clelland v. Robb* 1911 SC 253, 256, per Lord President Dunedin and Lord Kinnear. The question in each case is whether the pursuer has established, or in the stage of the present appeal has relevantly averred, such facts as involve the existence of such a relation of duty.[18]

Liability of manufacturers was recognised by the courts in certain clearly-defined cases.[19] Lord Macmillan considered the application of the law giving rise to a duty, as it was at the time, and determined that as there was no contractual relation between the manufacturer and Ms Donoghue, so a duty would only arise if the circumstances fell into one of the two exceptional cases: Whether the ginger beer was inherently dangerous, or whether it was known by the manufacturer to be dangerous.[20] His Honour then stated the law:

> The appellant in the present instance asks that her case be approached as a case of delict, not as a case of breach of contract. She does not require to invoke the exceptional cases in which a person not a party to a contract has been held to be entitled to complain of some defect in the subject-matter of the contract which has caused him harm. The exceptional case of things dangerous in themselves, or known to be in a dangerous condition, has been regarded as constituting a peculiar category outside the ordinary law both of contract and of tort. I may observe that it seems to me inaccurate to describe the case of dangerous things as an exception to the principle that no one but a party to a contract can sue on that contract.

[18] Ibid 602.

[19] Ibid 579-80 (Lord Atkin). For example, Lord Atkin referred to the decision of Brett MR in *Heaven v Pender* (1883) 11 QBD 503, 509.

[20] *Donoghue v Stevenson* [1932] AC 562, 602.

> I rather regard this type of case as a special instance of negligence where the law exacts a degree of diligence so stringent as to amount practically to a guarantee of safety.[21]

Lord Atkin proposed the neighbour principle, 'the rule that you are to love your neighbour becomes in law, you must not injure your neighbour'.[22]

> You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law, is my neighbour? The answer seems to be persons who are so closely and directly affected by my act that I ought to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.[23]

Lord Atkin considered cases that involved liability for negligence and sought principles from the decided cases that could be extended by analogy to provide authority for the finding of a remedy for Ms Donoghue.[24] The neighbour principle, based on principles that were believed to be accepted by society in general,[25] provided the basis for the *ratio* on the liability of manufacturers[26] upon which the court could award a remedy to Ms Donoghue.

> A manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.[27]

Lord Atkin also argued that this was common sense[28] and that if no remedy could be awarded in circumstances where a manufacturer, through negligence in the manufacture of the product, had injured a consumer, then the consumer would have no recourse against

[21] Ibid 611.
[22] Ibid 580.
[23] Ibid.
[24] Ibid 584-587.
[25] Ibid 583, 599.
[26] Ibid 599.
[27] Ibid.
[28] Ibid 583, 599.

anyone.[29] Lord Atkin, Lord Thankerton and Lord Macmillan found in favour of Ms Donoghue while Lord Buckmaster and Lord Tomkin dissented.

A characteristic of the common law is the binding nature of prior decisions regarding the interpretation and application of the law.[30] In this way, it could be argued that over time, paradigms are developed for the different causes of action and these need to be robust because future decisions that may test and apply the paradigms, must ultimately be made in the same way as past decisions. Despite the facts of each case being different, the legal principles for the relevant cause of action are applied to resolve the dispute.

For the purpose of this thesis, it is argued that the court will experience substantial difficulty applying existing legal principles to the new and unique facts of a dispute where the defendant has a neural interface device. As a result, the court will need to consider the application of the current law to this novel legal issue, like that experienced in *Donoghue*,[31] where the application of the current law cannot be applied without re-evaluation or adaptation of the existing law, or application of a new principle in order for the court to provide the remedy it believes is appropriate. While what will occur could not be described as a paradigm shift, it will be a development of common law principles applied to circumstances not previously envisaged. The House of Lords in *Donoghue*[32] considered the issue of duty of care but the analysis of the current law undertaken in this thesis considers all elements of negligence and attribution of liability. Determination of the research hypothesis requires a theory of reasoning that recognises the effect of tension on existing legal principles. For this reason, the theory of revolutionary science as enunciated by Thomas Kuhn,[33] is applied to the analysis of the legal issues throughout the thesis.

[29] Ibid 582-3.

[30] Alastair MacAdam and John Pyke, *Legal Institutions and Method* (LexisNexis Butterworths, 4th ed, 2010) 163 [4.5].

[31] [1932] AC 562.

[32] Ibid.

[33] Kuhn, above n 2.

Law is not science, but Morris Raphael Cohen argued convincingly that the functions of deduction in scientific method are prevalent in the law:

> First. It enables us to develop the implications of propositions and thus find out their true meaning. Knowledge grows most rapidly when we can properly utilize previous knowledge. Those who know make the most discoveries.
>
> Second. Deduction helps to make our assumptions explicit and this makes possible a critical attitude towards them, and
>
> Third. Deduction enables us to deal, not only with the actual, but with the possible. It thus liberates us to explore the field of possibility where there are to be found many things better than the actual.[34]

Cohen states that, for example, 'A deductive system which enables us to derive many legal rules from a few principles makes the law more certain, so that people can better know their rights.'[35] However, unlike science that can 'suspend judgment where adequate knowledge is wanting, the law is under the necessity of making immediate decisions.'[36]

When describing normal science, as opposed to revolutionary science, Kuhn stated that a network of commitments - conceptual, theoretical, instrumental and methodological, encourages the scientist to further articulate the theories being challenged by 'pockets of apparent disorder'.[37] This network of commitments 'is a principal source of the metaphor that relates normal science to puzzle-solving.'[38] Kuhn recognised that rules within a specialisation may have shortcomings but 'rules, I suggest, derive from paradigms, but paradigms can guide research even in the absence of rules.'[39] Kuhn then identifies crises that are results anomalous to the applicable paradigm. He believes that these crises 'are a necessary precondition for the emergence of novel theories.'[40]

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[34] Morris Raphael Cohen, 'Law and Scientific Method' in Scott Brewer (ed), *Scientific Models of Legal Reasoning* (Routledge, 2013) 231, 235.

[35] Ibid 236.

[36] Ibid 239.

[37] Kuhn, above n 2, 42.

[38] Ibid.

[39] Ibid.

[40] Ibid 77.

In response to these crises and their impact on the current paradigm, Kuhn states in respect of scientists that:

> Though they may begin to lose faith and then to consider alternatives, they do not renounce the paradigm that has led them into crisis … The act of judgment that leads scientists to reject a previously accepted theory is always based upon more than a comparison of that theory with the world. The decision to reject one paradigm is always simultaneously the decision to accept another, and the judgment leading to that decision involves the comparison of both paradigms with nature *and* with each other.[41]

Over time, the anomalies become fully congruent within the new paradigm.[42] Kuhn regarded the long period of time it took before there was acceptance of Newton's laws of motion and gravitation by scientists as examples of the time required for the paradigm to be universally accepted.[43]

> When, for these reasons or others like them, an anomaly comes to seem more than just another puzzle of normal science, the transition to crisis and to extraordinary science has begun. The anomaly itself now comes to be more generally recognized as such by the profession. More and more attention is devoted to it by more and more of the field's most eminent men.[44]

> Within the new paradigm, old terms, concepts, and experiments fall into new relationships one with the other ... What had previously been meant by space was necessarily flat, homogeneous, isotropic, and unaffected by the presence of matter. If it had not been, Newtonian physics would not have worked. To make the transition to Einstein's universe, the whole conceptual web whose strands are space, time, matter, force, and so on, had to be shifted and laid down again on nature whole.[45]

This process of paradigm shift is the essence of revolutionary science. Revolutionary science involves the existence of an accepted paradigm, the occurrence of anomalies that conflict with the paradigm giving rise to a crisis that requires the acceptance of a new

[41] Ibid.
[42] Ibid 77-8.
[43] Ibid 78.
[44] Ibid 82.
[45] Ibid 149.

paradigm.[46] Legal reasoning is not identical to scientific method, however, the application of the concept of revolutionary science will enable a determination of whether the current law will be challenged when applied to a civil dispute where the defendant has a neural interface device. The difficulty in applying the current law may result in, what Kuhn regards as, a crisis and this may in turn require acceptance of new law. In determining the research hypothesis, the theory of revolutionary science was applied.

3 *Methodology*

The methodology conducted in the thesis engaged both doctrinal research methodology[47] and empirical research methodology using a systematic, interactive forecasting technique known as the Delphi Method.

(a) Doctrinal Research

The research undertook a thorough review of the literature. There is substantial literature about the legal principles of negligence, including manufacturer liability, but there is no discussion of these legal principles in the context of neural interface devices. The thesis examines the civil legal issues that arise in connection with the use of neural interface devices by focussing on negligence.

Taking the legal proposition that the conventional application of the law of negligence is inadequate to fully resolve civil liability issues with neural interface devices, the doctrinal research has provided a methodological explanation of the rules governing these areas of law, an analysis of the relationship between these rules, an explanation of the areas of difficulty and insight into future changes in the law to accommodate neural interface innovation.

This approach included legal analysis of authoritative decisions, legislation and secondary material. The principal jurisdiction considered was Australia and where relevant, the analysis included the United States of America, Canada and the United Kingdom because a

[46] Ibid 208.

[47] Pearce D, Campbell E and Harding D, *Australian Law Schools: A Discipline Assessment for the Commonwealth Tertiary Education Commission* (AGPS, 1987), [9.10] – [9.15].

comparative analysis of these common law jurisdictions is in keeping with Australian courts' recognition of these decisions as persuasive.[48]

The literature enabled the research to:

- Identify a specific neural interface device or range of devices that exist or are currently being researched and developed.
- Investigate the legal issues that arise in the use of neural interface devices.
- Examine judgments that have resolved disputes based on these issues or analogous issues.
- Determine the degree to which the current law can adequately resolve these issues, in particular, liability where the device and human element are virtually indistinguishable.
- Where the legal issue cannot be completely resolved within the current legal framework, suggest changes that will assist in the resolution of the legal issue.
- Determine the extent to which manufacturers of neural interface devices can minimise their liability for adverse events.

The relevant literature has been included in the analysis provided in each chapter.

(b) The Delphi Method Research

The Delphi Method was used to provide the doctrinal research analysis with some verification. The Delphi Method research was used as a qualitative, community based participatory technique[49] to predict the legal issues that will arise and the possible solutions to those issues in the context of civil proceedings when there is a combination of human being and neural interface device. The Delphi Method research was an effective way of benefiting from the knowledge and judgment of legal experts in the judiciary, legal profession and university law schools without seeking statistical validity as required by quantitative

[48] Chief Justice Murray Gleeson, 'Global Influences on the Australian Judiciary' (Paper presented at the Australian Bar Association Conference, Paris, 8 July 2002) <http://www.hcourt.gov.au/assets/publications/speeches/former-justices/gleesoncj/cj_global.htm>; Kit Barker et al, *The Law of Torts in Australia* (Oxford University Press, 5th edition, 2012), 14 (in relation to UK decisions).

[49] Leavy, above n 15, 20-21.

research techniques.[50] The Delphi Method research undertaken, by its very nature, was original and the results are provided and analysed in chapter 3.

Norman Dalkey of the Rand Corporation in Santa Monica, California developed the Delphi Method in the 1950s for use in a United States commissioned military project[51] that was then used and analysed in further research which he undertook.[52] The method elicits and refines group judgments based on the rationale that 'two heads are better than one … when the issue is one where exact knowledge is not available.'[53] Linstone and Turoff define the Delphi Method as 'a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem.'[54] From their vast experience in using the Delphi Method at the University of Calgary in Canada, Skulmoski and Hartman have witnessed how the method has 'evolved into a flexible research method' making it an appropriate mechanism for a wide variety of research.[55] Skulmoski and Hartman are of the opinion that the 'Delphi Method works especially well when the goal is to improve our understanding of problems, opportunities, solutions, or to develop forecasts.'[56] They have recorded many research projects that used the Delphi Method, including one 'to identify the principle legal issues facing the computer forensics discipline within the Australian context.'[57]

The Delphi Method research undertaken is provided in chapter 3. In summary, a 'stimulus', that is, the information provided to participants to ensure the legal experts would understand the research questions sufficiently to accurately address the issues was developed. In

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[50] Harold A Linstone and Murray Turoff, 'Introduction' in Harold A Linstone and Murray Turoff (eds) *The Delphi Method: Techniques and Application* (Linstone and Turoff, 2002) v, 4.

[51] Gregory Skulmoski and Francis Hartman, 'The Delphi Method for Graduate Research' (2007) 6 *Journal of Information Technology for Education* 1, 2.

[52] Norman Dalkey, *The Delphi Method: An Experimental Study of Group Opinion* (The Rand Corporation, 1969).

[53] Ibid v.

[54] Linstone and Turoff, above n 50, 3.

[55] Skulmoski and Hartman, above n 51, 1.

[56] Ibid.

[57] Ibid 7. That project was Angela Brungs and Rodger Jamieson, 'Identification of legal issues for computer forensics' (2005) 22(2) *Information Systems Management* 57. In addition, the Delphi Method has been used in the following legal research: Chris Evans, 'Unravelling the mysteries of the oracle: using the Delphi methodology to inform the personal tax reform debate in Australia' (2007) 5(1) *eJournal of Tax Research*, 105; Chris Evans, Professor of Taxation at the University of New South Wales was successful in obtaining a 2007-08, ARC Linkage International (Delphi study) (with B Tran-Nam and R Bird); Glenn Ross and Bernie Tucker, *Inquiry into law enforcement integrity models* <http://www.aph.gov.au/~/media/wopapub/senate/committee/aclei_ctte/completed_inquiries/2008_10/lawenfmod/submissions/sub015_pdf.ashx>.

Round 1 of the Delphi Method research, participants were provided with the stimulus and asked specific questions. The participants provided answers to those questions and identified the legal issues that would arise. The participants also anticipated how the current law would resolve the legal issues they had identified. In Round 2, participants were provided with the legal issues identified by the participants in Round 1 and they allocated some value of importance to each of the legal issues.

The results of the Delphi Method research provided a foundation upon which legal analysis was undertaken[58] and provide a valuable contribution to knowledge in this rapidly evolving field.

4 *The Framework of this Thesis*

The foundation upon which the analysis in this thesis is built is the current Australian law, both common law and legislation, and the operation of neural interface devices. There are other legal issues introduced in this chapter that might arise but are beyond the scope of this thesis. These are strict liability, discrimination, privacy, data protection and wireless interception. Chapter 2 examines the technical aspects of neural interface devices while chapter 3 deals with the Delphi Method research undertaken where legal experts provide insight to the legal issues that will arise with the use of neural interface devices and the ways the law could address these issues. The civil liability principles of negligence, including manufacturer liability, are examined in relation to the development and use of neural interface devices and are analysed in chapters 4 and 5. Chapter 6 provides recommendations and, like chapter 1, introduces further research opportunities beyond the scope of this thesis. These are neuroethics, neurolaw and neuroscientific evidence. For the purposes of the thesis, the person with the neural interface device is taken to be a defendant in all the causes of action. This enables the applicable legal principles to be applied to the person with the neural interface device to determine whether or not liability can be established. In circumstances where the manufacturer of the neural interface device might also be a defendant, attribution of liability is considered. Particular scenarios involving a person with a neural interface device are provided to assist in applying the current law to the dispute, consequently in determining the research hypothesis. A more comprehensive introduction to the contents of each chapter follows.

[58] See chapters 4 and 5.

Chapter 2 examines the technology underlying the operation of neural interface devices and their limitations, both of which impact on the application of the current law. Chapter 2 explains how the human brain communicates with every part of the body by sending neural impulses through the central nervous system. Chapter 2 also explains that neural interface devices include a technical system that enables the recording of neural impulse, interpretation by a neural processor or decoder of what the brain is asking the specific body part to do and then the neural processor instructs the assistive device, such as an artificial neuroprosthetic limb, to operate in the way the brain intended.[59] In advanced neural interface devices the neural processor or decoder can also interpret feedback from the assistive device and communicate this feedback to the brain.[60] The recording and interpretation of neural impulses can be done through a sensor that is either placed inside the body through invasive surgery, such as a brain implant,[61] or applied to the outside of the body, such as a peripheral electromyography sensor.[62]

A neural impulse is targeted communication from the brain to a specific body part. It is not muscle movement in an arm, for example, that is being interpreted but the neural impulse to the body part. The neural impulses sent from the brain are sensed at the nerve endings in the arm.

Neural interface devices such as the bionic eye or bionic ear, pictured below in Figures 1.5 and 1.8, respectively, send information to the brain through the nervous system to enable the person to see or hear more clearly. Advanced neuroprosthetic limbs send sensory messages to the brain that enable the person to pick up objects without damaging the object. Communication from the neural processor to the assistive device occurs either by direct wiring or wirelessly. Wireless connectivity might enable the person greater freedom to move and is necessary to communicate with a robotic exoskeleton, for example, the Bionic Spine shown in Figure 1.7. The interpretation of neural impulse by the neural processor or decoder is a complex, scientific process that is yet to be fully mastered,[63] so this will impact on liability

[59] See Figure 1.1. Design of a Neural Interface Device.

[60] See Figure 3.2 Neural Interface System.

[61] For example, BrainGate Co, *About BrainGate* (2018) <https://www.braingate.org/about-braingate/>.

[62] Biometrics Limited, *Surface EMG* (2015) <http://www.biometricsltd.com/semg.htm?gclid=CN763taZ49UCFY8kvQodteUHBA>.

[63] Warren M Grill, Sharon E Norman and Ravi V Bellamkonda, 'Implanted Neural Interfaces: Biochallenges and Engineered Solutions' (2009) 11 *Annual Review of Biomedical Engineering* 1, 10.

in civil proceedings such as negligence.[64] However, development will help to avoid misinterpretation of neural impulses and the resulting unwanted action.

There will be more opportunities for the connection of the human brain with neuroprosthetic and robotic devices in the future. There are many other neural interface devices that are now being used and outcomes of research efforts may produce many more including the development of vision prosthesis using lasers.[65]

Such sophisticated technology and integration of machine with the human body raise legal issues. Clausen believes that '[m]elding brain and machine makes the latter an integral part of the individual'.[66] Søren Holm and Teck Chuan Voo believe that legal issues arise if it becomes impossible to distinguish between the will of the person and the operation of the technology, where the natural neural system assimilates with the technology.[67] This thesis contributes to the sparse amount of literature on legal liability in this area of technological innovation.

In chapter 3, the Delphi Method research, as discussed above,[68] provides the platform for the legal analysis undertaken[69] by seeking insight from legal experts in the judiciary, the legal profession and university law schools throughout Australia.[70] This original research provides outcomes that inform the analysis in chapters 4 and 5 and adds support to recommendations advanced in chapter 6.

Chapter 4 analyses the application of the three elements of negligence: Duty of care, breach and damage, to a person with a neural interface device. The research considers whether neural interface devices and their incorporation with the human body is so radically different or unique from other circumstances previously considered by the courts, that the law should recognise a different or unique application of the law of negligence. Of particular interest is

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[64] Mijail Serruya and John Donoghue, 'Design Principles of a Neuromotor Prosthetic Device' in Kenneth W Horch and Gurpreet S Dhillon (eds), *Neuroprothetics: Theory and Practice* (World Scientific Publishing Co, 2004) 1158, 1158.

[65] Brad Collis, 'Bionic eye hope from a touch of light' (2011) July *Swinburne* 16, 16. This research is undertaken by researchers at Swinburne University of Technology.

[66] Clausen, above n 4, 1080.

[67] Søren Holm and Teck Chuan Voo, 'Brain-Machine Interfaces and Personal Responsibility for Action – Maybe Not As Complicated After All' (2010) 4(3) *Studies in Ethics, Law, and Technology*, Article 7, 2-3.

[68] Under the heading '(b) The Delphi Method Research'.

[69] See chapters 4 and 5.

[70] See chapter 3.

the standard of care when determining whether there has been a breach of the duty of care and factual causation[71].

The analysis considers whether the standard of care applied to the person with a neural interface device will be different from that applied to a person without such a device. Civil Liability Legislation[72] now provides the factors that are used to establish the standard of care reflecting what, in common law, is that of a reasonable person of ordinary prudence in the same, or similar, circumstances.[73] The standard of care of a person with a neural interface device, analysed in chapter 4,[74] might ultimately be:

> (a) Higher than that for a person without such a device because of the expertise that might be necessary to facilitate the safe use of the neural interface device, that is, the user has undertaken extensive training in the operation of the neural interface device;
>
> (b) The same as a person without such a device (in an environment where the existence of the neural interface device might not be known so the individual should be regarded as a reasonable person without the device); or
>
> (c) Lower than that for a person without such a device - but this creates problems for the public so there would need to be compelling reasons for this change.

The impact of Civil Liability Legislation on negligence in the context of a person with a neural interface device is considered throughout chapter 4.[75] Whether or not the inference of negligence (*res ipsa loquitur*) applies when the defendant is a person with a neural interface

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[71] See analysis in chapter 4 under the headings '*1* Standard of Care' and '*1* Factual Causation', respectively.

[72] *Civil Law (Wrongs) Act* 2002 (ACT) ('*CLWACT*'); *Civil Liability Act 2002* (NSW) ('*CLANSW*'); *Civil Liability Act 2003* (Qld) ('*CLAQ*'); *Civil Liability Act 1936* (SA) ('CLAS'); *Civil Liability Act 2002* (Tas) ('*CLAT*'); *Wrongs Act 1958* (Vic) ('*WAVIC*'); *Civil Liability Act 2002* (WA) ('*CLAWA*'); ('Civil Liability Legislation'). The Northern Territory does not have similar legislation but the *Personal Injuries (Liabilities and Damages) Act* (NT) applies to personal injuries. The Long Title states 'An Act to modify the law relating to the entitlement to damages for personal injuries, to clarify principles of contributory negligence, to fix reasonable limits on certain awards of damages for personal injuries, to provide for periodic payments of damages for personal injuries, and for related purposes.'

[73] *Glasgow Corporation v Muir* [1943] AC 448, 454; *Bolton v Stone* [1951 AC 850, 860; *Paris v Stepney Borough Council* [1951 AC 367, 384. See also Carolyn Sappideen, and Prue Vines, (eds), *Fleming's The Law of Torts* (Thomson Reuters (Professional) Australia, 10th edition, 2011), 123 [7.10].

[74] See under the heading '*1* Standard of Care'.

[75] Particularly under the heading '*B* Statutory Modification of the Common Law'.

device is discussed[76] and thorough analysis on the determination of causation is also provided.[77] The complexity of ascertaining whether or not the cause of the accident was solely that of the individual or of the neural interface device is explored. It is recognised that the courts will have difficulty establishing the degree to which the neural interface device can be attributed to the injury because of its integration with the brain of the person. For this reason, the issue of liability of the manufacturers of these devices and attribution of liability between the person and the manufacturer of the device is considered in chapter 5.

Chapter 5 analyses manufacturer liability with respect to neural interface devices. This includes analysis of the product certification process through the law administered by the Therapeutic Goods Administration (TGA).[78] The research examines the extent to which the certification obligations will impact on attribution of liability to the manufacturers of neural interface devices and the recipients of these devices. Chapter 5 also considers manufacturer liability if the neural interface device is considered to operate beyond what is traditionally regarded as a tool.[79]

Chapter 6 presents the determination of the research hypothesis. Informed by the discussion, analysis and findings in chapters 2, 3, 4 and 5, it comprises of recommendations to assist in the application of the common law and legislation in the resolution of civil proceedings involving a party with a neural interface device. Recommendations regarding neural interface accreditation by the TGA are also provided. Chapter 6 also acknowledges that there are a vast number of legal, ethical and public policy issues that are beyond the scope of this thesis but provides an introduction to further research opportunities in neurolaw, neuroethics and neuroscientific evidence.

D *Other Considerations Outside the Scope of this Thesis*

Australia is the jurisdiction upon which the current law is assessed. While other common law jurisdictions have been considered where appropriate, the outcomes of the research are applicable solely to the Australian jurisdiction. It is anticipated that other common law jurisdictions will be able to draw some value from this thesis where similar law exists.

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[76] See chapter 4 under the heading '*4* Whether the Inference of Negligence (res ipsa loquitur) Applies'.

[77] See chapter 4 under the heading '*D* Causation'.

[78] See under the heading '*1* TGA Approval'.

[79] See under the heading '*2* Neural Interface Device Beyond Being a Tool'.

The research focusses on the civil liability of a person with, and where appropriate, the manufacturer of, a neural interface device. Those involved in the training of a person with the neural interface device or those who may impact on the effective operation of the device are identified but not included in the analysis. Product liability[80] through the application of the *Australian Consumer Law* (*ACL*)[81] is also excluded as manufacturer liability is analysed where the neural interface device operates as it should without any safety defect or malfunction. The research focussed on the neural interface device working according to the manufacturer's specifications as this provides a more compelling analysis than one that involves malfunction of the device. For this reason, malfunction or a safety defect is expressly excluded in the Delphi Method research.

Ethical considerations will impact on the medical profession when neural interface devices are sought by individuals to enhance human abilities. There may be many other ethical considerations that arise with respect to the provision and use of neural interface devices but these fall outside the scope of this thesis.[82] It is acknowledged that the civil causes of action examined in this thesis are determined by the courts in a very fact specific environment and so outcomes of legal analysis using the scenarios selected will be limited in application to civil disputes. The outcomes of this thesis will, however, provide insight and recommendations that will assist the resolution of civil disputes where the defendant has a neural interface device.

Neural interface devices differ in construction and operation so the specificity of the neural interface device considered in legal analysis throughout the thesis, and the Delphi Method research, is grounded in the fundamental, operational characteristics of neural interface devices that interpret neural impulse and communicate feedback to the brain. It is acknowledged that the specific technical attributes of the neural interface device involved in the dispute will be of importance in determination of liability, but the legal analysis undertaken in this thesis will assist future investigations.

The assistive device that constitutes part of a neural interface device might be robotic but the analysis of robotics is beyond the scope of this thesis. The primary focus of analysis is

[80] See explanation in chapter 5 under the heading '*A* Introduction'.

[81] *Competition and Consumer Act 2010* (Cth) sch 2 ('*Australian Consumer Law*').

[82] See the introduction of neuroethics in chapter 6 under the heading '*1* Neuroethics'.

the neural interface aspect of the neural interface device as it is the interpretation of neural impulse by the decoder, the resulting instructions sent to the assistive device and the feedback provided to the brain from the device that will be of primary importance in determining liability for harm. While interfacing with an external computer or robot is possible, the focus of the thesis is on neural interface devices that are fully integrated with the human body to the extent that they no longer exist as a separate and independent device. It is upon this basis that existing law regarding tools, which are not integrated with the human body, cannot be adequately or appropriately applied. It is acknowledged that the operation of robots through neural impulse, including the degree of autonomous functionality that the robot possesses, will present further facts that might be considered in future civil disputes. However, these types of robots are beyond the scope of this thesis.

Although doctrinal methodology was applied in the legal analysis, policy considerations were introduced where relevant. It is acknowledged that while judicial reasoning often includes policy considerations, application of the established legal principles ensures the courts are resolving disputes on the basis of legal principles. The policy considerations discussed will also inform the legislature, however, the analysis of policy considerations in the context of political implications is beyond the scope of this thesis.

Finally, the legal issues arising with neural interface devices include negligence, and manufacturer liability, are analysed in chapters 4 and 5, respectively. However, there are a number of other issues that are beyond the scope of this thesis. These issues include changes to the legislative framework that impact on neural interface devices with respect to strict liability, compulsory third party insurance, discrimination, data protection, privacy and wireless interception. These legal issues were considered early in the research and, despite them being beyond the scope of this thesis, a summary of these issues highlights the breadth of impact neural interface devices will have on different areas of law. The summary also provides insight into the opportunity for future research.

1 *Strict Liability*

Strict liability has traditionally been applied in situations where the activity being undertaken is seen to present extraordinary risk to others but society decides to tolerate the activity ‘on

condition that it pays its way regardless of whether it is carried out with due care or not'.[83] However, Sappideen and Vines believe strict liability has been, and remains, 'unorganised and fragmentary in application', as the Australian courts have 'openly endorsed it only in cases where the non-negligent creation of risk arises from an *abnormal* activity'.[84] Activities for which strict liability has been applied include product liability,[85] aviation[86] and dangerous things that escape such as electricity,[87] gas,[88] oil,[89] fire explosives[90] and acid smuts[91]. Workers' compensation and road accidents are the dominant areas of activity in which strict liability is applied through legislation.[92]

While it could be argued that the integration of a neural interface device with a human being is currently *abnormal*, it is difficult to conclude that a person living and moving with such a device is actually engaged in *abnormal* activity. Consequently, strict liability is unlikely to be applied to such a person unless it is in unison with compulsory third party liability insurance, as is the case with motor vehicles.[93]

Despite strict liability being beyond the scope of this thesis, inference of negligence[94] is considered in chapter 4 in the analysis of negligence and neural interface devices.

2 *Compulsory Third Party Insurance*

In recognition of the possible dangers in the use of neural interface devices, as discussed in chapters 2 and 4, parliament might consider introducing legislation requiring persons with these devices to obtain compulsory third party liability insurance.[95] This would be to protect

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[83] Sappideen and Vines, above n 73, 380 [14.20].

[84] Ibid 381 [14.20].

[85] *Competition and Consumer Act 2010* (Cth).

[86] *Damage by Aircraft Act 1999* (Cth).

[87] *Eastern & S African Telegraph v Cape Town Tramways* [1902] AC 381.

[88] *Batcheller v Tunbridge Wells Gas Co* (1901) 84 LT 765.

[89] *Protection of the Sea (Civil Liability) Act 1981* (Cth); *Smith v Gt W Rly* (1926) 135 LT 112.

[90] *Burnie Port Authority v General Jones* (1994) 179 CLR 520.

[91] *Halsey v Esso Petroleum* [1961] 1 WLR 683. See also Sappideen and Vines, above n 73, 390 [15.30].

[92] Each State and Territory throughout Australia has workers compensation and motor vehicle accident legislation. See also, Sappideen and Vines, above n 73, 381 [14.20]; 382-91 [14.30]-[15.30].

[93] *Imbree v McNeilly* (2008) 236 CLR 510, [129], [130], [180], [181] (Kirby J).

[94] *Res ipsa loquitur*. See chapter 4 under the heading '*4* Whether the Inference of Negligence (res ipsa loquitur) Applies'.

[95] *Imbree v McNeilly* (2008) 236 CLR 510, [129], [130], [180], [181] (Kirby J).

the public from damage or injury caused to their property or person, similar to the compulsory third party insurance required of motor vehicle owners. If this was to happen throughout Australia, it could be argued, as Kirby J in *Imbree v McNeilly* (*Imbree*)[96] did, that the legislation is to inform the content of the common law rule when deciding that the person's standard of care to the public.

> The latter invite attention to the statutory context in which the common law duty of care owed by a driver on a public road in Australia falls to be defined. That context includes the universal operation of compulsory third party insurance of broad similarity operating throughout the nation. It is well past time, in this special context, that this reality should be acknowledged as affecting the existence and content of the duty of care owed by the driver of a motor vehicle to others reliant on that driver's skill.[97]

Third party insurance was raised by two of the legal experts in the Delphi Method research and is subsequently mentioned in chapters 3 and 4, however, full analysis of public policy factors, coherency of the law, indeterminate liability and social utility, that might influence the court's consideration of this type of insurance, is not undertaken.

3 *Discrimination*

The objects of the *Disability Discrimination Act 1992* (Cth)[98] are to protect individuals from discrimination on the basis of their disability. The legislation ensures that persons with disabilities have the same fundamental rights as the rest of the community. 'Disability' is defined to include loss of physical and mental functions[99] within which a person with a neural interface device would be included. Even if it could be argued that the person with a neural interface device no longer has the physical disability, the definition ensures that the disability includes one that has 'previously existed but no longer exists'.[100]

Disability also includes a condition that 'is imputed to a person'. A person with a neural interface device could be considered to have a disability because the device is not a biological part of the human body and may not function in the identical manner as the body

[96] Ibid 549 [129], 549 [130], 563-4 [180] and 564 [181].
[97] Ibid 564 [181].
[98] *Disability Discrimination Act 1992* (Cth) s 3.
[99] Ibid s 4.
[100] Ibid s 4(i) under the definition of *Disability*.

party it is replacing.[101] Behaviour of a person with a neural interface device that is a 'symptom or manifestation' of having the device is regarded as a disability.[102]

On the basis of having a disability, a person with a neural interface device might be discriminated against in many and varied environments and circumstances, including sport, work but analysis regarding discrimination is beyond the scope of the thesis. Further research could be undertaken to explore the role of governments to ensure compliance with anti-discrimination legislation. This could include communication to employers, sporting organisations and the public informing of the operation of neural interface devices and the ways in which those individuals with the devices can be ensured freedom from discrimination. In addition, people who are seeking to obtain these innovative neural interface devices might also experience discrimination in breach of the *Disability Discrimination Act 1992* (Cth) but analysis regarding this discrimination is beyond the scope of the thesis. Further research could be undertaken to examine the impact on compliance with anti-discrimination legislation if the government were to monitor the particulars of individuals who seek to receive neural interface devices ensuring that restrictions on receipt of the device are solely on legally valid grounds, such as age and capacity to give informed consent.

4 *Data Protection/Privacy*

Neural interface devices will interpret commands from the person in the form of neural impulses which will be matched to previously recorded and coded instructions. The technology involved is discussed in chapter 2. The recording of the instructions and operation of the device will be retained to enable the developers to monitor the use of the neural interface device. The developer might use this data to refine the accuracy of the device in interpreting the commands sent to the device by the person and improve the technology in future development.

The permitted uses of the data collected from the device should be carefully considered and it may be necessary to ensure that consent for the use of that data has been received from the person with the neural interface device. The data would be regarded as personal

[101] Ibid s 4(k) under the definition of *Disability*.
[102] Ibid s 4.

information as it is recording the actions of the person.[103] This in turn is recording how a person is living and moving.

For example, through the use of a mobile phone and other GPS devices it is now possible to track the location of persons with Alzheimer's disease and dementia and to chart their movement over a period of time.[104] Similar technology is being used to track different bodily functions in order to better treat people with conditions such as epilepsy and diabetes.[105] An examination of the data may provide a deep insight into the life of the person with the device. Significant privacy concerns arise, and where this data is viewed by individuals other than those who require it for the treatment of the person with the device or improvement of the device, unintended consequences might occur. For example, the data may be used by marketers, health insurance providers, law enforcement and others in a way that may compromise the privacy and rights of the person with the neural interface device. Therefore, consent from the neural interface device recipient should be required in any agreement that deals with the supply, maintenance and replacement of the device regarding:

- Access to the information in the device.
- The ways in which the information in the device can be used.
- The organisations and individuals to whom the information in the device can be provided.
- The specific information that can be provided to other organisations and individuals.

Not only is there a question of who accesses the data stored in the neural interface device but how it is accessed and what use is made of the information. In addition, incidental disclosure of private information, unintended data leaks and malicious data theft pose threats to privacy of the person with a neural interface device.[106] Further research could be

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[103] Personal information is defined in *Privacy Act 1988* (Cth) s 6:

> Information or an opinion about an identified individual, or an individual who is reasonably identifiable:
>
> (a) whether the information or opinion is true or not; and
>
> (b) whether the information or opinion is recorded in a material form or not.

[104] Alzheimer's Australia, *Tracking and Monitoring Devices* (27 July 2017) <https://www.fightdementia.org.au/files/NATIONAL/documents/GPS-tracking-and-monitoring-devices.pdf>.

[105] Epilepsy Foundation, *The Role of Seizure Alerts* (10 April 2015) <http://www.epilepsy.com/learn/impact/mortality/sudep/role-seizure-alerts>. Dario Health, *Dario Blood Glucose Management System* (2018) <http://intro.mydario.net.au/?gclid=CLa3tfmO-NMCFdWkvQod6-4FYg>.

[106] Marcello Ienca, 'Brain Machine Interfaces, Artificial Intelligence and Neurorights' (2017) 3 *BrainInsight* <https://brain.ieee.org/newsletter/2017-issue-3/brain-machine-interfaces-artificial-intelligence-neurorights/>.

undertaken to assess the issues of access to, and use of, information stored in neural interface devices and whether this should be prohibited, subject to compliance with the Australian Privacy Principles[107] and the consent from the neural interface device recipient. Following the work of Professor Jack Balkin of Yale Law School, the possible recognition of the existence of a fiduciary duty owed to the recipient of the device by those who have access to the information in a neural interface device could also be examined.[108]

5 *Wireless Interception*

The technical operation of a neural interface device is discussed in chapter 2. The neural impulse is recorded and decoded by the neural processor that then sends instructions to the assistive device, such as a neuroprosthetic arm. Privacy issues may also arise if the instructions being sent from the neural processor to the assistive device can be intercepted wirelessly. It may also occur if the neural interface device has been incorporated into the human body through the use of invasive surgery, in a procedure similar to the implantation of a heart pacemaker, and where the neural processor can be monitored or altered wirelessly. For example, the Cochlear Baha 4 Sound Processor is a wireless-enabled, fully programmable head-worn digital sound processor for the Baha Implantable Bone Conduction Hearing System.[109]

The interception of telecommunication signals by carrier services are controlled by the *Telecommunications Act 1997* (Cth). The interception of wireless communication between a neural processor and assistive device could constitute a carriage service under the Act if the communication is regarded as electromagnetic energy.[110] Through the wireless communication with the assistive device, a third party may be able to control the movement of the neural interface device independent from the person to whom the device is connected. This may result in unwanted, unnecessary or dangerous activity for which the person with the neural interface device should not be held accountable. Manufacturers should endeavour to provide security and to restrict such access, however, this may not always be possible so protection mechanisms, such as emergency shutdown or shut off may be

[107] The Australian Privacy Principles are contained in the *Privacy Act 1988* (Cth) sch 1.

[108] Jack Balkin, 'Information Fiduciaries and the First Amendment' (2016) 49(4) *UC Davis Law Review* 1183.

[109] Australian Government, *Prostheses List* <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>.

[110] *Telecommunications Act 1997* (Cth) s 7.

incorporated in the neural interface device. Analysis of wireless interception in the operation of neural interface devices is beyond the scope of the thesis.

Chapter 2 highlights research being undertaken including a National Institutes of Health (NIH) grant that has been provided to Dr Leigh Hochberg to develop the wireless capabilities of a neural interface device, BrainGate, discussed below.[111] Further research could be pursued to examine the possibility that the neural interface device incorporated into the human body through invasive surgery might be able to be monitored or altered wirelessly. That research could consider specific legislative provisions to prohibit the unauthorised interception of wireless communication in a neural interface system, an advanced concept of hacking.

E *Application of this Thesis*

The application of this thesis will be most significant when a dispute comes before the court and the defendant has a neural interface device. Contribution to the knowledge in the application of the current law to this developing technology will assist the courts, the legal profession and the legislature to anticipate re-evaluation and adaptation of the current law to enable resolution of disputes. Neural interface devices are becoming a reality, as the following examples confirm, and it is only a matter of time before a civil action is commenced against a person with a neural interface device.

The creation of 'neurotechnologies to evaluate and treat nervous system disorders and to restore lost neural functions' is occurring 'at the intersection of neuroscience, computer science, engineering and medicine'.[112] There are a broad range of neural interface devices being developed, each modified to the task of utilising neural impulses to command an assistive device. One neural interface device, which is currently undergoing clinical trials in the United States, is a brain implant called BrainGate, see Figure 1.3.[113] BrainGate has been developed for people who cannot move or communicate. The technology upon which this

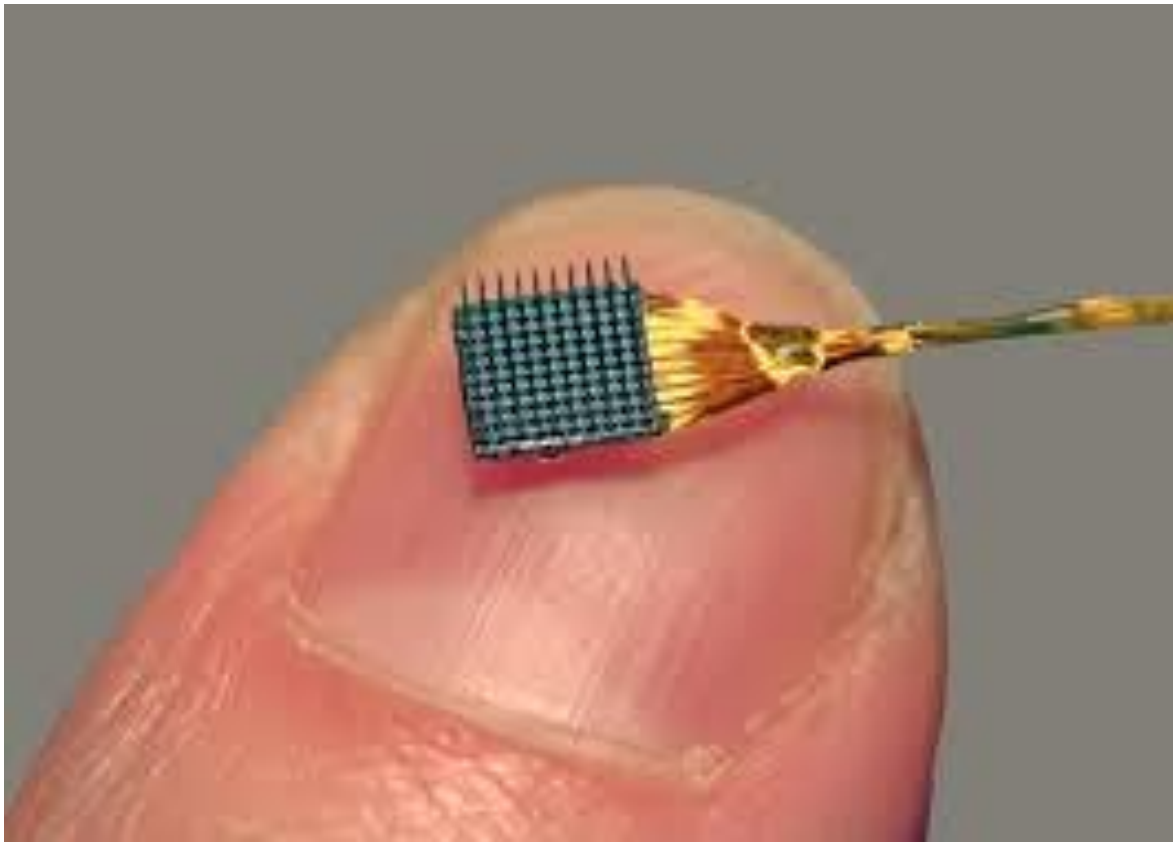
[111] David Orenstein, *Brown, partners earn NIH BRAIN grant for wireless neural interfaces* (9 October 2015) News from Brown <https://news.brown.edu/articles/2015/10/braingategrant>.

[112] John P Donoghue, above n 12.

[113] BrainGate Co, *Thought* (2009) <http://www.braingate.com/thought/>.

neural interface device was created is the 'ability to sense, transmit, analyse and apply the language of neurons.'[114]

Figure 1.3 BrainGate's Neural Sensor[115]



Source: Allison McCann, *Mind Over Matter: Envisioning a World of Thought-Controlled Computing* (2012) Scienceline <http://scienceline.org/2012/01/mind-over-matter/>.

BrainGate enables individuals who cannot move to use a computer or control a wheelchair, telephone and many other assistive devices using thought alone.[116] For example, in research, captured in Figure 1.4, a recipient of BrainGate could direct a modular prosthetic arm known as 'Mobius Bionics' LUKE[117] arm' (LUKE arm) and a robotic arm (DLR

[114] Ibid.

[115] Allison McCann, *Mind Over Matter: Envisioning a World of Thought-Controlled Computing* (2012) Scienceline <http://scienceline.org/2012/01/mind-over-matter/>.

[116] Office of Media Relations, Brown University, 'Brown Scientist John P. Donoghue Wins Major Neuroscience Award' (Press Release, 20 August 2007) <http://news.brown.edu/pressreleases/2007/08/neuroscience-award>.

[117] Mobius Bionics, *The LUKE Arm* (2018) <http://www.mobiusbionics.com/>.

Lightweight Robotic Arm)[118] to grasp a cup enabling the person to drink coffee in the way she had not been able to do since becoming paralysed fourteen years earlier.[119]

Figure 1.4 BrainGate and the DLR Lightweight Robotic ArmOperating in Unison[120]

Source: Leigh R Hochberg et al, 'Reach and Grasp by People with Tetraplegia Using a Neurally Controlled Robotic Arm' (2012) 485 *Nature* 372, 372.

[118] DLR is the Institute of Robotics and Mechatronics of the German Aerospace Center. See DLR Institute of Robotics and Mechatronics <https://www.dlr.de/rm/en/desktopdefault.aspx/tabid-8017>.

[119] Leigh R Hochberg et al, 'Reach and Grasp by People with Tetraplegia Using a Neurally Controlled Robotic Arm' (2012) 485 *Nature* 372, 372.

[120] Ibid.

The LUKE arm is a neuroprosthetic arm, that can also operate robotically and has been commercially available since late 2016, see Figure 1.5.[121] Both BrainGate and the LUKE arm are examined in chapter 2.[122]

Figure 1.5 The LUKE Arm

Source: Mobius Bionics, 'The LUKE Arm' <http://www.mobiusbionics.com/luke-arm/>; Anon, *Mobius Bionics to Bring DEKA's LUKE Prosthetic Arm to Market: Mobius Bionics announces the launch of its groundbreaking prosthetic arm beginning late 2016* (8 July 2016)' BusinessWire <http://www.businesswire.com/news/home/20160708005511/en/Mobius-Bionics-Bring-DEKA%E2%80%99s-LUKE-Prosthetic-Arm>.

Another neural interface device is the bionic eye that has been developed by Bionic Vision Australia, see Figure 1.6.[123] The bionic eye will enable individuals with vision impairment caused by diseases such as retinitis pigmentosa and age-related macular degeneration to

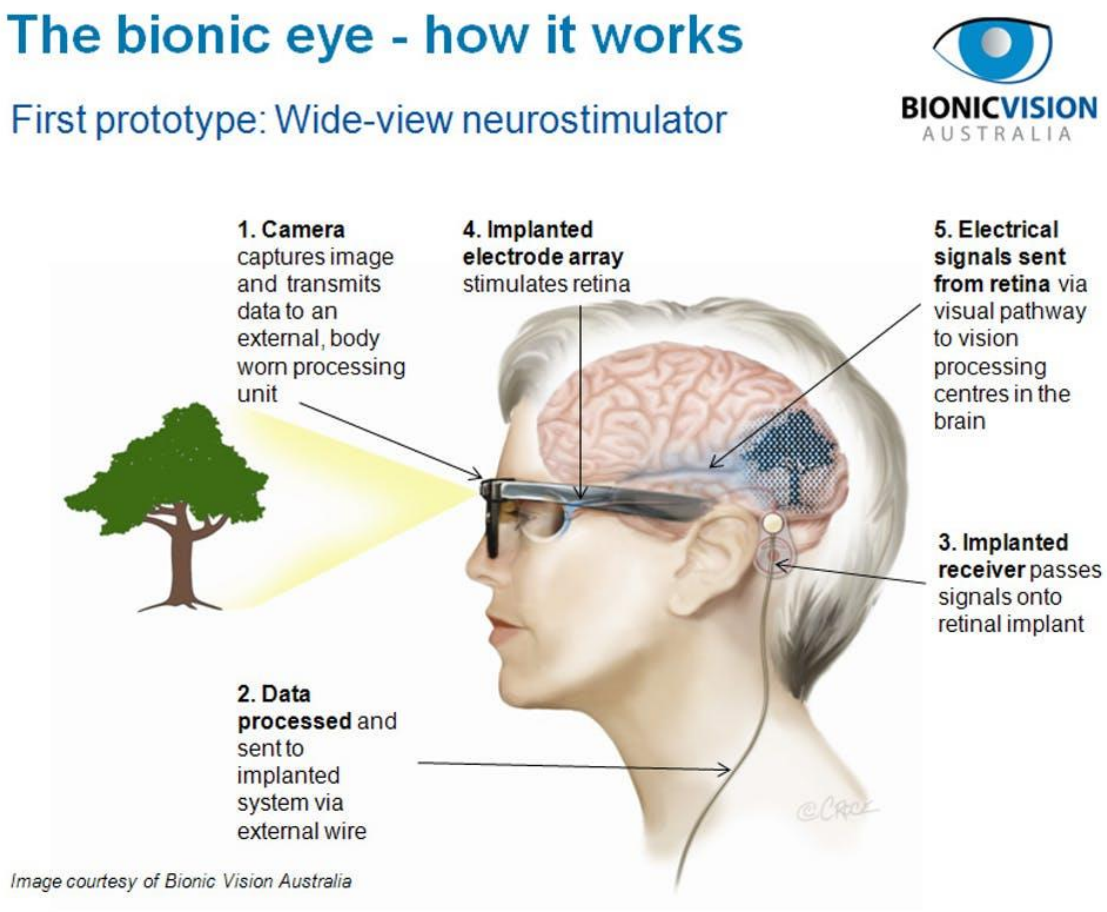
[121] Mobius Bionics, 'The LUKE Arm' <http://www.mobiusbionics.com/luke-arm/>; Anon, *Mobius Bionics to Bring DEKA's LUKE Prosthetic Arm to Market: Mobius Bionics announces the launch of its groundbreaking prosthetic arm beginning late 2016* (8 July 2016)' BusinessWire <http://www.businesswire.com/news/home/20160708005511/en/Mobius-Bionics-Bring-DEKA%E2%80%99s-LUKE-Prosthetic-Arm>.

[122] See analysis under the heading '*1* Invasive Neural Interface Devices'.

[123]Bionic Vision Australia, *Bionic Vision Australia Ceases Operations* (2016) <http://bionicvision.org.au/>. Bionic Vision Australia was a consortium of some of Australia's leading universities and research institutes, and funded by the Australian Research Council from 2010, ceased operations on 31 December 2016. The technologies developed by the consortium are now being commercialised by Bionic Vision Technologies Pty Ltd (BVT). See Bionic Vision Technologies, *Bionic Vision Technologies* <www.bionicvis.com>.

regain a sense of vision.[124] Continuing scientific research will improve the technology to provide a clearer picture of the world.

Figure 1.6 The Bionic Eye[125]



Source: Anthony Burkitt, 'Bionic Vision: The Fight for Sight' *The Conversation* (2011) <http://theconversation.com/bionic-vision-the-fight-for-sight-236>.

Dr Mark Humayun, Professor of Ophthalmology at the University of Southern California, together with colleagues, has developed a system called Argus which enables patients who have lost their sight through retinitis pigmentosa, to see edges and shapes.[126] Using a complex array of video signals, electrical impulses and interface with the brain, success was achieved and the technique is being developed.[127]

[124] Institute of Electrical and Electronics Engineers, Inc (IEEE), *Engineering in Medicine and Biology Society* (2018) Neural Engineering <http://www.embs.org/about-biomedical-engineering/our-areas-of-research/neural-engineering>.

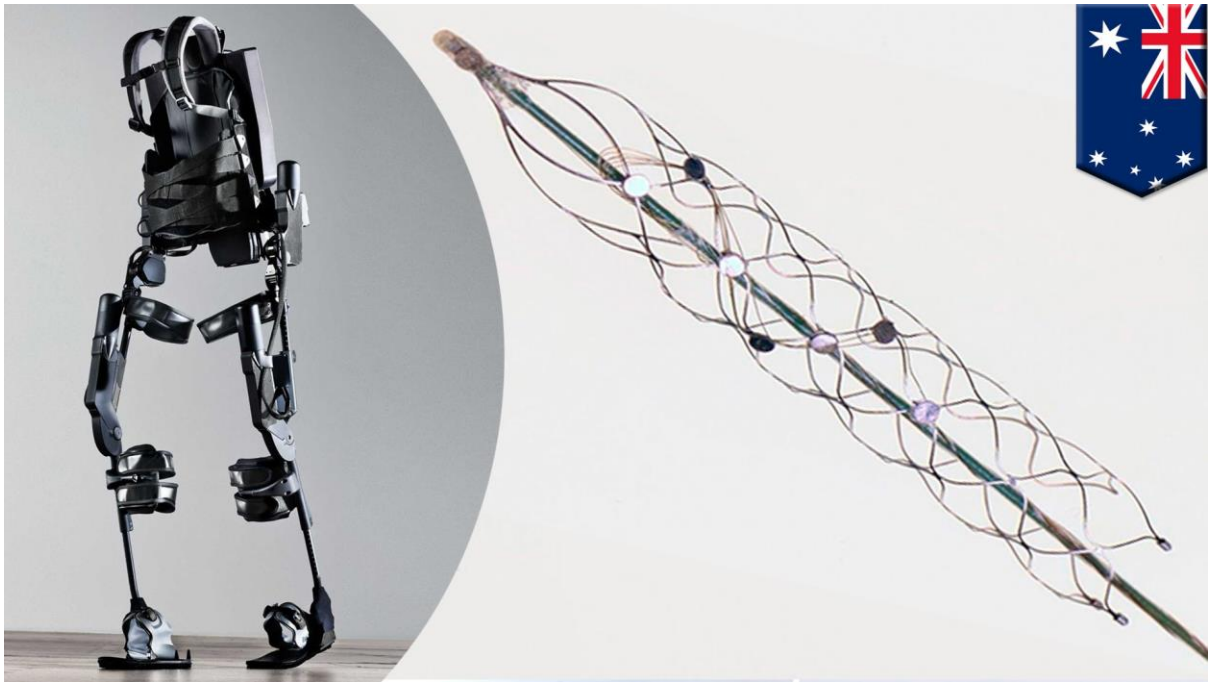
[125]Anthony Burkitt, 'Bionic Vision: The Fight for Sight' *The Conversation* (2011) <http://theconversation.com/bionic-vision-the-fight-for-sight-236>.

[126] Josh Fischman, 'bi-on-ics' (2010) January *National Geographic* 34, 51.

[127] Ibid.

Of particular interest to people with severe back injuries, including those with paralysed limbs, is the development of the Bionic Spine, see Figure 1.7, that interfaces with a robotic exoskeleton to provide movement of a person's paralysed legs. Robotic exoskeletons are technological skeletons that surround the body and enable movement directed by the person's thoughts. The Bionic Spine commenced clinical trial in 2017 and is being developed by neurologists and biomedical engineers from the Royal Melbourne Hospital, Melbourne University and the Florey Institute of Neuroscience and Mental Health.[128]

Figure 1.7 The Bionic Spine[129]



In relation to the Bionic Spine, the helical structure, pictured on the right above, is the stent-based electrode that is positioned on the brain that records and interprets neural impulse and then sends commands to a transmitter in the chest of the person that connects wirelessly to an exoskeleton, pictured on the left, facilitating movement of people with paralysis.[130]

Source: Jane Gardiner, 'Moving with the Power of Thought' (2017) *Pursuit* <https://pursuit.unimelb.edu.au/articles/moving-with-the-power-of-thought>.

Other mind-controlled exoskeletons are being developed. At the World Cup 2014 in São Paulo, Brazil, Juliano Pinto, who is a paraplegic, wore a mind controlled exoskeleton,

[128] Jane Gardiner, 'Moving with the Power of Thought' (2017) *Pursuit* <https://pursuit.unimelb.edu.au/articles/moving-with-the-power-of-thought>.

[129] Ibid.

[130] Ibid.

developed by the Duke University Center for Neuroengineering,[131] and made the ceremonial kick off.[132] See Figure 1.8.

Figure 1.8 Juliano Pinto using mind-controlled exoskeleton at the World Cup 2014 in San Paulo[133]

Source: Neurogadget, *Paraplegic Man in Mind-Controlled Robotic Suit Kicks Off World Cup 2014* (2014) <http://neurogadget.net/2014/06/13/paraplegic-man-mind-controlled-robotic-suit-kicks-world-cup-2014-video/10434>.

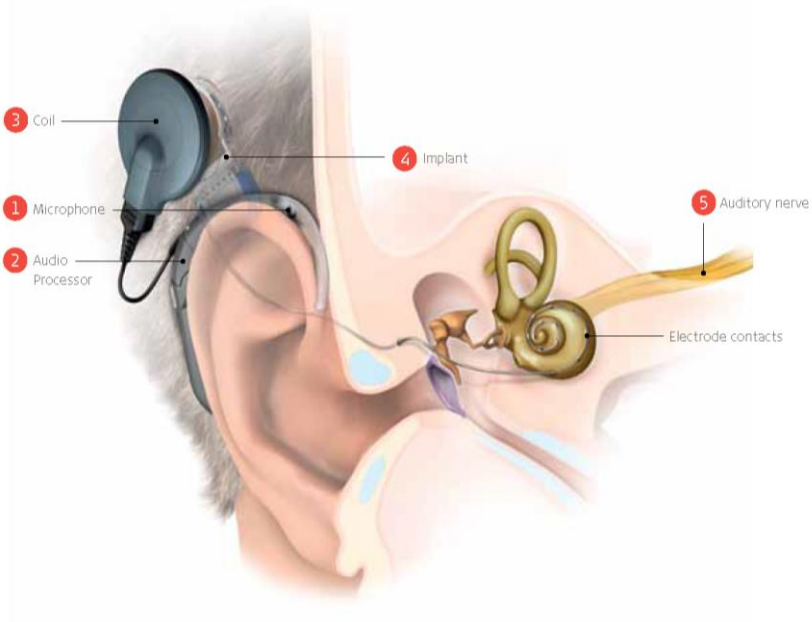
[131] Miguel A L Nicolelis, 'Mind in Motion' (2012) 307(3) *Scientific American* 58.

[132] Martins and Rincon, above n 14. SuperRoboHead, *Paraplegic Wearing Robot Suit Kicks Off World Cup in Brazil* (13 June 2014) YouTube <https://www.youtube.com/watch?v=inCvbDLfXBo>.

[133] Neurogadget, *Paraplegic Man in Mind-Controlled Robotic Suit Kicks Off World Cup 2014* (2014) <http://neurogadget.net/2014/06/13/paraplegic-man-mind-controlled-robotic-suit-kicks-world-cup-2014-video/10434>.

The Australian bionic ear (or cochlear implant), see Figure 1.9, manufactured by Cochlear Ltd is providing restored hearing capabilities for those with hearing difficulties.[134]

Figure 1.9 The Bionic Ear[135]



How a Cochlear Implant System Works

Cochlear implant systems convert everyday sounds into coded electrical pulses. These electrical pulses stimulate nerve fibres in the cochlea. The auditory (hearing) nerve transmits the signals to the brain where they are interpreted as sound. The implant continuously stimulates at very high speed. As the brain receives sound information instantaneously, sounds are heard as they occur.

1. Sounds are picked up by the microphone in the audio processor.
2. The audio processor analyses and codes sounds into a special pattern of digital information.
3. This information is sent to the coil and is transmitted across the skin to the implant.
4. The implant interprets the code and sends electrical pulses to the electrodes in the cochlea.
5. The auditory nerve picks up the signals and sends them to the auditory centre in the brain. The brain recognises these signals as sound.

Source: Med-El, *Understanding Cochlear Implants* <http://s3.medel.com/downloadmanager/downloads/maestro_2013/en-GB/20329.pdf>.

[134] Cochlear Ltd, *Cochlear's Range of Solutions* (2018) <http://www.cochlear.com/wps/wcm/connect/au/home/discover>.

[135] Med-El, *Understanding Cochlear Implants* <http://s3.medel.com/downloadmanager/downloads/maestro_2013/en-GB/20329.pdf>.

Essentially, neural interface devices provide an opportunity for individuals who have suffered some physiological or neurological disease, disorder or injury to interact with the world around them. While products being developed by neuroscientists are currently to assist those individuals who require the product for medical reasons, there is the possibility of incredible advancements that give rise to both excitement and trepidation for the community. There are neuroscientists who believe that brain implants to facilitate the merging of minds and machines will become the norm.[136] The legal frameworks that exist will be challenged by these circumstances so the analysis provided in this thesis seeks to address these challenges. These include the difficulties of determining the commands, in the form of neural impulse, that were sent by the individual to the neural sensor and decoder. This will impact on the instructions that are subsequently sent to the assistive device.

In relation to the complexity of the neural interface devices, it is possible that through the efforts of software engineers and computer scientists, cognitive computing may produce a neural interface device that can "think" for itself.[137] With cognitive computing the operation of the computer is not confined to a lineal process dictated solely by the algorithms. The computer moves beyond the algorithms, and like the human brain, accesses information from many sources simultaneously to determine the best decision to the challenge presented.[138]

The difficulty for law and policy makers is to develop or modify the current legal and social frameworks to enable the benefits of neural interface devices to be enjoyed by society rather than to hinder or prohibit such technological innovation. This thesis is a concerted effort to anticipate the future as there is a lack of civil case law specifically on the research topic. It is for this reason that the Delphi Method has been employed and chapter 3 provides insight gained through the Delphi Method research from legal experts on the legal issues that might arise. Existing case law and regulatory frameworks provide a platform from which recommendations for the development of the law are possible. The legislature should also consider the legal issues that could arise from the use of neural interface devices. However, the legal experts involved in the Delphi Method research advise against legislative

[136] Malcolm Gay, *The Brain Electric* (Text Publishing, 2015) 28, 30.

[137] Jerome Pesenti, 'Cognitive Computing' (Speech delivered at TEDx, Bermuda, 4 December 2014) <https://www.youtube.com/watch?v=8zYp4yH4PoQ>.

[138] Ibid.

interference in this innovative field for fear of adverse impact on device development and availability.

There exists a tension between the common law and legislation. While legislation can be swiftly enacted, there can be adverse effects on the common law. On the other hand, legislation may address legal issues that would take the common law many years to effectively establish principles in order to fully address the legal issue. Those tensions were recognised, for example, when the Australian Law Reform Commission (ALRC) proposed in 2014 a new statutory cause of action in tort, 'serious invasion of privacy'.[139] Barbara McDonald, who led the ALRC inquiry, believed that breaches of privacy will arise in civil actions and legislation would be the preferred mechanism to deal with these breaches. If left to the courts, '[a] difficult case will come up and it may well be that the law will then develop more strictly than some people would like.' [140] However, Attorney-General George Brandis said that 'The government has made it clear on numerous occasions that it does not support a tort of privacy'.[141]

Further tension between the common law and legislation was considered in 2016, when Brandis requested the ALRC to conduct an inquiry on the encroachment of common law rights by Commonwealth legislation.[142] The Terms of Reference for the inquiry were to 'identify Commonwealth laws that encroach upon *traditional* rights, freedoms and privileges' and 'to critically examine those laws to determine whether the encroachment was appropriately justified.'[143] President of the ALRC, Rosalind Croucher, said:

> By reading *down* laws to minimise possible encroachments on rights and freedoms, the common law – through statutory interpretation – plays a role in protecting them ... This has become known as the principle of legality … [but it] does not, however, constrain legislative power.[144]

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[139] Australian Law Reform Commission, *Serious Invasions of Privacy in the Digital Era*, Discussion Paper 80 (2014) 62-3 [4.42].

[140] Ibid.

[141] Chris Merritt, 'Brandis Rejects Privacy Tort Call' *The Australian* 4 April 2014, 27.

[142] Australian Law Reform Commission, *Traditional Rights and Freedoms – Encroachments by Commonwealth Laws*, Report No 129 (2015).

[143] Rosalind Croucher, 'Encroachments on Freedoms – The ALRC Freedoms Inquiry' (Speech delivered at the NSW Bar Association, Sydney, 10 November 2016) <https://www.alrc.gov.au/news-media/speech-presentation-article/encroachments-freedoms#>.

[144] Ibid.

The ability of legislation to qualify or extinguish rights and freedoms by clear words exists but parliament can be held politically accountable and can be voted out of power.[145] The ALRC looked at justification through two lenses, procedural and substantive, and 'concluded that proportionality tests offered a valuable way of *structuring critical analysis*, particularly as part of that rights-mindedness that should become the normal way of thinking.'[146] The ALRC identified many laws that put rights or principles at risk 'including freedoms of speech, religion, association and movement, property rights, non-retrospectivity of laws, fair trial and procedural fairness, burden of proof, right to silence, privilege of legal communications and the right to judicial review.'[147]

It is likely, therefore, that parliament will be reluctant to interfere with the current law that will apply to neural interface devices because of the political difficulty and possible adverse repercussions. Government interference in common law litigation has had mixed results. The Accident Compensation Scheme in New Zealand is an example of where a plaintiff does not get as much as they might be awarded by the court and the political and social costs are undesirable.[148] It is a no-fault compensation scheme for injury resulting from an accident that is not limited to motor vehicle accidents[149] but extends to sexual violence or a condition caused by work.[150] The scheme design is similar to Australian state-based workers compensation schemes.[151] A 2007 PriceWaterhouseCoopers review of this scheme concluded that it 'adds considerable value to New Zealand society and the economy and performed very well in comparison to alternate schemes in operation internationally'.[152] However, by 30 June 2010, the scheme was $10.3 billion in debt. Morrison identified the predicament of the New Zealand government, 'No government wants to be in a position where a poor choice of scheme model results in major unfunded liabilities which must be corrected, ultimately through taxpayer funds.'[153]

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[145] Ibid.

[146] Ibid.

[147] Simon Rice, 'Brandis receives long list of rights-limiting laws – now can he justify them?' *The Conversation* (2015) <https://theconversation.com/brandis-receives-long-list-of-rights-limiting-laws-now-can-he-justify-them-45645>.

[148] Ibid.

[149] *Accident Compensation Act 2001* (NZ) s 25.

[150] New Zealand Government, *Injuries we Cover* <https://www.acc.co.nz/im-injured/injuries-we-cover/what-we-cover/?smooth-scroll=content-after-navs>.

[151] Simon Morrison, 'The New Zealand No-Fault Accident Compensation Scheme' (2013) 114 *Precedent* 39, 42.

[152] PriceWaterhouseCoopers, *Accident Compensation Corporation New Zealand Scheme Review* (2007), i.

[153] Morrison, above n 151, 42.

While government policy initiatives might focus on producing a balance of what is good for everyone versus just the individual, arguing that it is problematic where the focus in society is on 'self', the decisions made will have political repercussions. Analysis throughout this thesis provides opportunities for the legislature and the legal profession to consider whether or not the development of law regarding neural interface devices should be through common law or legislation.

To some degree there will be trial and error, as is often the case in terms of the development of new technology. The case law will evolve. It is highly likely that with this new technology, government will pursue a light touch regulatory approach to avoid interfering with the application of the current Civil Liability Legislation by the court.

Through neuroscientists, engineers, lawyers, academics and politicians working together, this exciting world of technological advancement and innovation can be realised.

> At their most ambitious, efforts to compensate for damaged or destroyed sensory organs have come to involve the invention, manufacture and implantation of bionic counterparts for eyes and ears. These connect the conscious mind and the vibrant, colourful, noisy external world - with life changing consequences for recipients.
>
> Once the stuff of science fiction, the bionic enterprise of today is built on a realisation that has transformed human innovation during the past decade; that no single discipline in science, engineering or medicine is up to the task. Instead, each specialist field has mastered some of the components needed to solve an overall problem, whether related to vision, hearing or any other among a spectrum of healthcare challenges.[154]

The challenges that the melding of mind and machine through neural interface present at law are analysed throughout this thesis. This thesis seeks to provide a substantial contribution to the legal literature that is both innovative and pioneering. This new, developing field of inquiry provides the opportunity for ground breaking advances in legal analysis and the evaluation of the existing legal frameworks that, in particular circumstances, will require re-evaluation and adaptation.

[154] Gio Braidotti, 'Medical Advances on Fast Forward', (2013) 4 *Monash – Delivering Impact* 10, 10.

II CHAPTER 2 NEURAL INTERFACE SYSTEMS AND DEVICES: THE FRAMEWORK

A *Introduction*

Chapter 1 provided an introduction to the development of neural interface devices. Chapter 2 provides an insight into the technical framework upon which neural interface devices operate. This chapter highlights the fact that there are serious limits to our knowledge of how the brain operates. Our technical ability to record, decode and replicate neural impulse is also limited so the integration of neural interface devices into the human being will challenge the application of the current law when determining civil liability for damage to property or injury to another.

For the purposes of the legal research and analysis in chapters 3, 4 and 5, it is important to have a basic understanding of the physiological dimensions of the human brain together with the technical specifications of neural interface devices. Accordingly, this chapter introduces the complexity of research in the area of neural interface devices in an effort to understand how they operate. The chapter discusses the current parameters of neural interface systems whereby the brain communicates with biomechanical machines to address and facilitate physical and neurological challenges faced by humans throughout the world.

The chapter then outlines the technical principles upon which these neural interface devices are based so that the limitations of the devices can be understood. The limitations of the neural interface devices play a fundamental role in challenging the application of the current law, so chapters 3, 4 and 5 will research and analyse that impact leading to recommendations and conclusions in chapter 6.

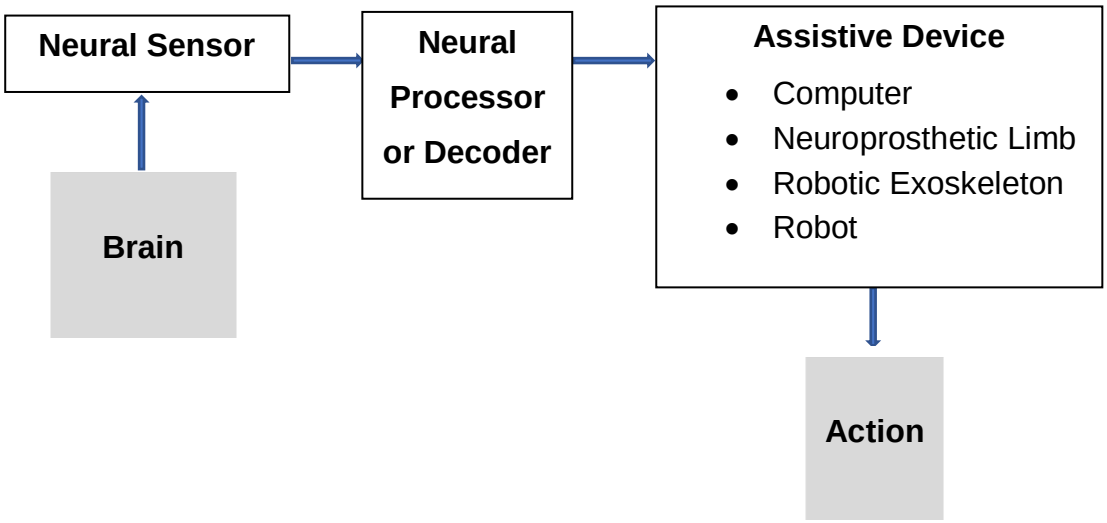
The following terms will be used:

> "**Neural interface system**" means the successful sensing of neural activity to provide a command signal to control computers, machines, or any of a range of prosthetic devices that span from physical to biological elements.[155]

[155] John P Donoghue et al, 'Assistive Technology and Robotic Control Using Motor Cortex Ensemble-Based Neural Interface Systems in Humans with Tetraplegia' (2007) 579(3) *Journal of Physiology* 603, 603-4.

"**Neural interface device**" is synonymous with "neural interface system" in that the components include a neural sensor, a neural processor or decoder and an assistive device, as illustrated below in Figure 2.1.

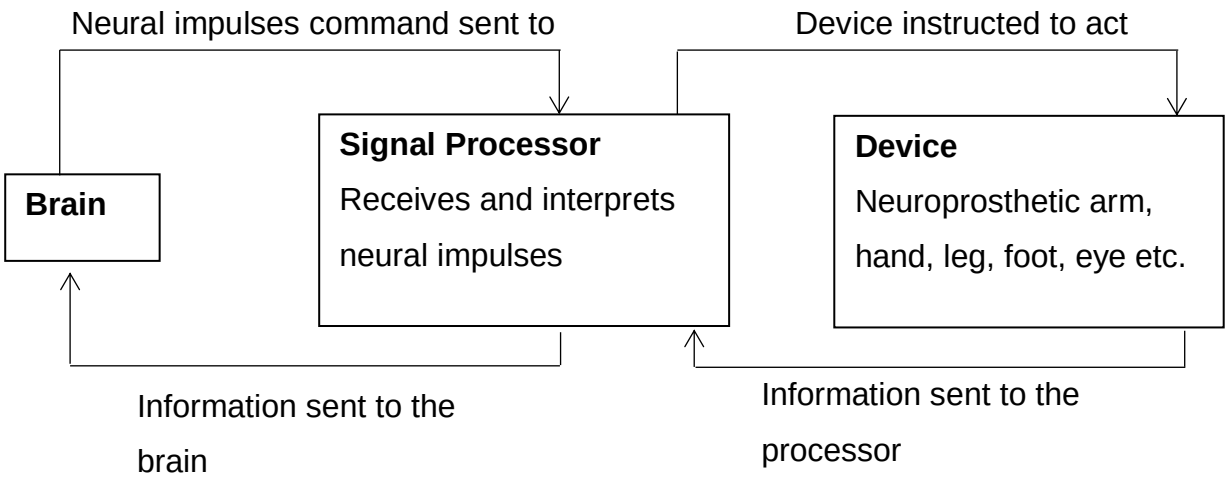
Figure 2.1 Design of a Neural Interface Device[156]



B *Neural Interface Systems and Devices*

The neural interface device that is the focus of this thesis has the full circle of communication between the brain and assistive device, as outlined in Figure 2.2.

Figure 2.2 Neural Interface System



[156] Adapted from Donoghue, above n 12.

However, the technical analysis in this chapter will focus on the components of a neural interface device identified in Figure 2.1 to enable the identification of the technical framework within which all neural interface devices operate. The neural interface devices that are the focus of this thesis have this technical framework but also the capability to send feedback to the brain

Before the brain can be used to direct an assistive device, the brain itself 'needs to be assembled, a remarkable feat of bioengineering'.[157] '[The] brain starts as nothing more than a layer of little round stem cells,' and its construction and renewal is 'a process known as neurogenesis.'[158] In his efforts to determine the cause of a patient's epilepsy, neurosurgeon, Eric Leuthardt inserted sensors into the patient's brain, seeking:

> the electric current of thought itself: the millions of electrical impulses, known as action potentials, that continuously volley between the brain's estimated 100 billion neurons. Those neurons are connected by an estimated 100 trillion synapses, the slender electrochemical bridges that enable the cranium's minute universe of cells to communicate with one another. Like an exponentially complicated form of Morse code, the cells of the brain exchange millions of action potentials at any moment, an electric language that physically underlies our every movement, thought, and sensation. These are not sentient thoughts, per se, but in sum this mysterious and crackling neural language is what makes consciousness possible – a sort of quantum programming code that remains all but unrecognizable to the consciousness it creates.[159]

To better understand how the brain works, research is being conducted throughout the world. For example, the Allen Institute for Brain Science in Seattle, USA is compiling the Allen Brain Atlas, a map of the brain's molecular machinery, charting the activity of protein-coding genes throughout the brain.[160] 'The Allen Institute aims to answer some of the biggest questions in neuroscience and accelerate research worldwide through public releases of

[157] Ivan Semeniuk, 'Solving the Mysteries of the Brain' *The Globe and Mail* (Vancouver), 17 January 2015, A11, A11.

[158] Ibid.

[159] Gay, above n 8, 4.

[160] Carl Zimmer, 'Secrets of the Brain' (2014) 225(2) *National Geographic* 28, 43.

new data, knowledge and tools.'[161] At the Allen Institute, Clay Reid is seeking to understand 'how information is encoded and processed in neural networks of the visual system, using behaviour, anatomy and physiology' and recently 'used a combination of imaging and anatomical approaches to investigate how the structure of neural connections relates to functional brain circuitry.'[162]

Jeff Lichtman, a neuroscientist at Harvard University, and his colleagues are generating, 'in collaboration with others, a complete map of the neural connections in the brain—known as the "connectome"'.[163] Lichtman has stated that:

> The cerebral cortex of the human brain contains more than 160 trillion synaptic connections. Each neuron receives synaptic connections from hundreds or even thousands of different neurons, and each sends outputs to a similar number of target neurons, spread out over a large distance. Thus, establishing the complete wiring diagram of even one type of neuron in the cortex poses enormous challenges.[164]

At the Martinos Center for Biomedical Imaging in Boston, USA, Van Wedeen unveiled the grid structure of the brain in 2012 and found that 'far from being just a tangle of wires, the brain's connections turn out to be more like ribbon cables — folding 2D sheets of parallel neuronal fibers that cross paths at right angles, like the warp and weft of a fabric.'[165]

> If grid structure guides connectivity similar to the lane markers in a highway, then navigation would be reduced from a general 3D problem to a far simpler question of when to exit. In the brain, fibers growing in any axis would have a choice at each moment of just the four orthogonal directions perpendicular to their course. Grid structure would increase the efficacy of path orientation as a mechanism of axonal path-finding. Simultaneously, this structure supports incremental modification of connectivity by geometric modification within broad

[161] Allen Institute for Brain Science, *Fueling Discovery*, 1 <https://alleninstitute.org/media/filer_public/69/96/6996313a-f498-40ac-9b40-c1741bc4fd01/aboutus_alleninstitutefactsheet_2015_updated.pdf>.

[162] Allen Institute for Brain Science, *Staff Profiles* (2018) <https://alleninstitute.org/what-we-do/brain-science/about/team/staff-profiles/r-clay-reid/>.

[163] Harvard University, *Jeff Lichtman, MD, PhD* (2018) <http://www.conte.harvard.edu/investigators/jeff-lichtman-md-phd/>.

[164] Ibid.

[165] National Institutes of Health, *Brain Wiring a No Brainer? Scans reveal astonishingly simple 3D grid structure – NIH-funded study* (29 March 2012) <https://www.nih.gov/news-events/news-releases/brain-wiring-no-brainer>. See also Van J Wedeen et al, 'The Geometric Structure of the Brain Fiber Pathways' (2012) 335(6076) *Science* 1628, 1630.

> continuous families of parallel paths. Thus, the grid organization of cerebral pathways may represent a "default connectivity," on which adaptation of structure and function can both occur incrementally in evolution and development, plasticity, and function.[166]

Despite this complexity and lack of knowledge, the ability to interface with the brain through brain computer interface, brain-machine interface and neural interface devices is being achieved.

> It's a union whose potential beggars the imagination: an unprecedented evolutionary step- effectively digitizing the body's nervous system - that conjures images of not only mental access to everyday objects like computer networks, appliances, or the so-called Internet of things but also telekinetic communication between people and cyborg networks connected by the fundamental language of neural code.[167]

Neural interface devices, through efferent and afferent communication[168] between the device and the brain, will enable the human mind to instruct and control assistive devices.[169] Throughout this thesis, the terms that will be used regarding communication between the different parts comprising the neural interface system will be: The brain sends 'commands' to the signal processor or decoder, that sends 'instructions' to the assistive device, that sends 'communication' back to the human brain via the signal processor/decoder.[170]

In relation to the terminology in the developing field of neural interface, John Donoghue and his co-authors stated:

> Devices that transform a neutrally based motor intention into a command signal that can operate physical systems have been called brain–computer interfaces (BCIs), brain machine interfaces (BMIs), and neuromotor prostheses (NMPs), among other names. No single term has yet been established in this emerging field. We use the term neural interface system here because all of these systems rely on successful sensing of neural activity to provide a command signal to control computers, machines, or any of a range of prosthetic devices that span from physical to biological elements. Thus, a sensing NIS is agnostic to whether the

[166] Van J Wedeen et al, above n 165, 1633.

[167] Gay, above n 8, 5.

[168] Information flowing from both the brain to the device and from the device back to the brain, respectively.

[169] Institute of Electrical and Electronics Engineers, Inc (IEEE) Engineering in Medicine and Biology Society, *Neural Engineering*, above n 124.

[170] See Figure 2.2 Neural Interface System.

> detected signal is used to control a wheelchair, a prosthetic limb, a computer, or biological elements including voluntary muscles or viscera such as bowel and bladder.[171]

Some ailments may limit a person's ability to move some or all of their limbs. These include disabilities sustained by a stroke, Alzheimer's disease, tetraplegics and other spinal cord injuries, neurofibromatosis 2, muscular dystrophy, cerebral palsy, amyotrophic lateral sclerosis (ALS), Parkinson's disease and other motor neuron diseases.[172] Despite sustaining physical disability, persons with these ailments maintain cerebral function which could be harnessed and benefited through neural interface devices.[173] One of the major goals of a neural interface system is to work as 'a kind of replacement part, or prosthesis, for the motor system'[174] that offers a physical means to reconnect action intentions to the world.

The ability for a neural interface device to interpret neural impulses and instruct an assistive device to respond as directed by the brain requires incredibly complex technology. The neural interface systems upon which neural interface devices operate include devices that sense brain signals, a signal processor or decoder and an assistive device to effect action, as illustrated in Figure 2.1 above.[175]

There are several neural interface devices that have been developed to assist people with ailments such as those stated above. 'Brain-machine interfaces are clinically well established in restoring hearing perception through cochlear implants.'[176] A computer cursor can be activated by patients with tetraplegia who can also use the neural interface device to control physical devices.[177] Development of technology that interfaces the brain with devices, such as the exoskeleton Mindwalker,[178] will assist accident victims, war veterans and individuals with ALS, Parkinson's disease and other neurological disorders that 'disrupt

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[171] Donoghue et al, above n 155, 603-4. 'NIS' means neural interface system.

[172] Ibid.

[173] Ibid.

[174] Ibid.

[175] Donoghue, above n 5, 512.

[176] Clausen, above n 8, 1080.

[177] Hochberg et al, above n 119, 372. The authors cite the following in support of this statement: Leigh R Hochberg et al, 'Neuronal Ensemble Control of Prosthetic Devices by a Human with Tetraplegia (2006) 442 *Nature* 164; John D Simeral et al, 'Neural control of cursor trajectory and click by a human with tetraplegia 1000 days after implant of an intracortical microelectrode array' (2011) 025027 *Journal of Neural Engineering* 8; Sung-Phil Kim et al, 'Point-and-Click Cursor Control with an Intracortical Neural Interface System by Humans with Tetraplegia' (2011) 19(2) *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 193.

[178] Shiqian Wang et al, 'Design and control of the MINDWALKER exoskeleton' (2015) 23(2) *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 277.

motor behaviours that impede arm reaching, hand grasping, locomotion and speech production.'[179]

The development of a neural interface device in combination with a robotic assistive device is also possible. The robotic assistive device could be any number of different computerised equipment including a wheelchair, artificial arm or indeed, a robot that may assist with specific tasks.[180] These types of robotic assistive devices controlled by the mind would be of assistance to those individuals who are unable to activate the device through functional stimulation, 'such as those with ALS or muscular dystrophy.'[181] Robotic wheelchairs will use 'decoded neural activity'[182] while robotic assistants, often called telerobots, can be controlled at a distance.[183] 'Semiautonomous telerobots could retrieve objects or perform other tasks for patients for whom wheelchair use is impractical.'[184]

The neural interface devices being developed take the form of invasive or non-invasive application. 'Invasive procedures implant electrodes directly into the brain' while 'noninvasive techniques use electrodes placed on the scalp to measure electrical activity.'[185]

1 *Invasive Neural Interface Devices*

An example of an invasive neural interface device is that used for deep brain stimulation (DBS) to treat people with end-stage Parkinson's disease.[186] 'Worldwide, more than 30,000 implants have reportedly been made to control the severe motor symptoms of this disease'.[187] DBS is an invasive technique that enables the adjustment of activity in specific circuits in the brain.[188] 'The method involves inserting a small electrode through the skull and placing its narrow tip adjacent to the desired circuit. The activity of the circuit can then be boosted or diminished by applying a small electric charge.'[189]

[179] Nicolelis, above n 131, 58.
[180] Serruya and Donoghue, above n 64, 1184.
[181] Ibid.
[182] Ibid.
[183] Ibid.
[184] Ibid.
[185] Hammock, above n 7.
[186] Clausen, above n 4, 1080-1081.
[187] Ibid 1080.
[188] Semeniuk, above n 157, A11.
[189] Ibid.

Bionic Vision Australia are developed an artificial retina that allows those with degenerative vision loss to regain a sense of vision.[190] Signals are sent from a camera, as an assistive device, to the implanted retina microchip.[191] The microchip produces small electrical currents, stimulating cells in the retina that are still functioning correctly, and then the optic nerve carries the information to the brain which interprets the information as an image.'[192] The Bionic Spine, introduced in chapter 1, involves a stent placed on the motor cortex of the brain and a mind controlled exoskeleton.[193]

The invasive neural sensor, Electrocorticography (ECoG), measures neural impulses from beneath the skull but above the cortex. ECoG grids do not pierce the brain but sit just below the tough outermost membrane enveloping the brain, known as the dura mater. Like electrodes, ECoG rest on the surface of the brain.[194] With Electrocorticograms, 'the electrodes are embedded in a thin plastic pad which is placed directly over the cortex, beneath the dura mater.'[195] The neural impulse is more clearly received the closer to the motor cortex the sensor is located. Close proximity of the neural sensor to the motor cortex can minimise incorrect decoding of the neural impulse command.

> Electrocorticography (ECoG) has recently gained attention as a recording technique for use in brain–computer interfaces. ECoG involves recording electrical signals from the surface of the human brain, typically in patients being monitored prior to surgery. ECoG is less invasive than neuronal recordings since the brain is not penetrated and has a much higher signal-to-noise ratio (SNR) than [Electroencephalography] EEG, as well as higher spectral and spatial resolution.[196]

The cochlear prosthesis is a neural interface device that directly stimulates the auditory nerve through electrodes placed along the nerve.[197] In addition, Dr Mark Humayun,

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[190] IEEE above n 124.

[191] Ibid.

[192] Ibid.

[193] Gardiner, above n 128.

[194] Gay, above n 8, 17.

[195] Serruya and Donoghue, above n 64, 1166.

[196] Pradeep Shenoy et al, 'Generalized Features for Electrocorticographic BCIs' (2008) 55(1) *IEEE Transactions on Biomedical Engineering* 273, 273.

[197] Duncan Graham-Rowe, 'Artificial Limbs Wired Direct to the Brain' (14 October 2006) *New Scientist* 30, 30.

Professor of Ophthalmology at the University of Southern California, together with colleagues, has developed a system called Argus which enables patients who have lost their sight through a disease known as retinitis pigmentosa, to see edges and shapes.[198] Using a complex array of video signals, electrical impulses and interface with the brain, success was achieved and the technique is being developed further with a device called "Orion I Visual Cortical Prosthesis" (Orion I).[199]

> Implanted on the surface of the visual cortex located within the occipital lobe of the brain, Orion will bypass the retina and optic nerve altogether. This potentially offers hope for treating patients with nearly all forms of blindness where the optic nerve or retina is completely damaged, as in glaucoma, diabetic retinopathy, retinal detachments, trauma, infection, and others.[200]

BrainGate, is also an invasive neural interface device that is implanted on the brain.[201]

(a) BrainGate

The work done by John P Donoghue, director of the Brain Science Program at Brown University, Providence, Rhode Island USA, has resulted in BrainGate, that has 'allowed people with paralysis to move a computer cursor, to read email, control a television, play video games, control a wheelchair or operate a robotic arm – using thoughts alone.'[202] BrainGate consists of an implantable sensor and external processors that record and decode brain signals from the motor cortex, turning these signals into movement commands that can control assistive devices.[203] The technology is now owned by BrainGate Co[204] and clinical trials of BrainGate2 are being conducted at four different locations in the United States.[205]

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[198] Josh Fischman, 'bi-on-ics' (2010) January *National Geographic*, 34, 51.

[199] Ibid.

[200] Second Sight Medical Products, Inc., 'Second Sight Announces First Successful Implant of Model of Orion I Visual Cortical Prosthesis' (Press Release, 8 April 2015) <http://investors.secondsight.com/news-releases/news-release-details/second-sight-announces-first-successful-implant-model-orion-i>.

[201] BrainGate Co, above n 113.

[202] Office of Media Relations, above n 116. See Figure 1.3 BrainGate's Neural Sensor.

[203] Ibid.

[204] BrainGate Co, above n 61.

[205] Massachusetts General Hospital, Case Western Reserve University, Providence VA Medical Center and Stanford University Medical Center <http://www.braingate.org/clinical-trials.

The BrainGate sensor 'consists of a silicon array about the size of a baby aspirin that contains approximately one hundred electrodes, each thinner than a human hair.'[206] BrainGate Co is working on development of thought controlled robotic devices and believe that 'next generation products may be able to provide an individual with the ability to control devices that allow breathing, bladder and bowel movements.'[207]

> In the current BrainGate™ System, a bundle consisting of one hundred gold wires connects to a pedestal which extends through the scalp. The pedestal is connected by an external cable to a set of computers in which the data can be stored for off-line analysis or analyzed in real-time. Signal processing software algorithms analyze the electrical activity of neurons and translate it into control signals for use in various computer-based applications.[208]

In 2015, members of the BrainGate team, Leigh Hochberg and Arto Nurmikko, were awarded a National Institutes of Health (NIH) grant of $US1.64m to research 'high-bandwidth wireless interfaces for continuous human intracortical recording.'[209] This research will 'push the envelope with BrainGate to make a fully implanted medical treatment system, freeing patients from externally tethered components, and giving them greater control over their home environments and daily lives.'[210] The project commenced on 30 September 2015 and will continue through to 30 June 2020.[211]

2 *Non-Invasive Neural Interface Devices*

EEG involves placement of electrodes on the scalp to measure neural activity and is non-invasive.[212] There are many other neural interface devices that are now being used and outcomes of research efforts may produce many more including the development of vision prosthesis using lasers by researchers at Swinburne University of Technology.[213]

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[206] BrainGate Co, *FAQ*' (2009) <http://www.braingate.com/faq/>.

[207] Ibid.

[208] Ibid.

[209] US Department of Health and Human Services, *Funding* (21 March 2018) <https://braininitiative.nih.gov/funding/investigator.htm>.

[210] Ibid. Project Number: 1UH2NS095548-01 <https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9054364>.

[211] US Department of Health and Human Services, *Project Information 1UH2NS095548-01*, <https://projectreporter.nih.gov/project_info_details.cfm?aid=9054364&icde=0>.

[212] John P Donoghue et al, above n 155, 604.

[213] Brad Collis, 'Bionic eye hope from a touch of light' (2011) July *Swinburne* 16, 16.

Dominic Rowe, neurologist at Macquarie University Hospital, has identified the perils for individuals with motor neuron disease who are unable to communicate or move despite their cognition, vision, hearing and senses being intact.[214] In response, a non-invasive neural interface device known as the NeuroSwitch device, created by Peter Ford, allows individuals with motor neuron disease to connect to the world through a computer by using electromyography (EMG) control.[215] In the development of NeuroSwitch, Ford made contact with Stephen Hawking, who had motor neuron disease, and Hawking used NeuroSwitch to communicate with the world.[216] NeuroSwitch is now used by many other individuals including United States veterans with acute spinal cord injuries.[217] In Australia, Ford has been collaborating with Peter Abolfathi, a bioengineer in Sydney, who has done some extraordinary work with another non-invasive neural interface device, an exoskeleton rehabilitative robotic glove.[218]

In 2012 the Duke University Center for Neuroengineering predicted that the light exoskeleton they were working on would envelop the legs of a paraplegic enabling them to become mobile, to walk and to perform the first ceremonial kick of the 2014 World Cup.[219] Indeed, 'Juliano Pinto, a 29-year-old with complete paralysis of the lower trunk, performed the [2014 World Cup] symbolic kick-off at the Corinthians Arena in Sao Paulo'.[220] Neural impulses were sensed by a cap on Pinto's head and instructions were then sent to the exoskeleton.[221]

The development of mind controlled exoskeletons is also being undertaken in other parts of the world. For example, researchers throughout Europe have developed Mindwalker:[222]

> The system implements BNCI (brain-neural-computer interface) technology, which can be used to convert either EEG signals from the brain, or EMG signals from patient's shoulder

[214] Malcolm Turnbull et al, *Australian Story: The First Word Transcript*, (25 February 2013) <www.abc.net.au/austory/content/2012/s3697596>.

[215] Ibid. EMG 'is the measurement of electrical activity associated with the activation of a muscle group as detected by non-invasive electrodes on the surface of the skin.' Control Bionics, *FAQ* (2019) <https://www.controlbionics.com/support-and-care/emg-technology-faqs/>.

[216] Turnbull et al, above n 214.

[217] Ibid.

[218] Ibid. Puya Peter Abolfathi, *Development of an Instrumented and Powered Exoskeleton for the Rehabilitation of the Hand*, (University of Sydney, 2007).

[219] Nicolelis, above n 131, 44. See also Figure 1.8 Juliano Pinto using mind-controlled exoskeleton at the World Cup 2014 in San Paulo.

[220] Martins and Rincon above n 132. SuperRoboHead, above n 132.

[221] Martins and Rincon, above n 132.

[222] Wang et al, above n 178.

> muscles, into electronic commands. The electronic commands are then used to control an exoskeleton attached to the user's legs. … The Mindwalker system also utilizes an innovative "dry" technology developed by Berlin-based company eemagine Medical Imaging Solutions, to read the EEG signals. This forgoes the need for invasive electrodes placed into brain tissue, or an awkward "wet" cap, in favour of a cap which is covered in electrodes. The cap can be fitted and worn without discomfort.[223]

Mindwalker has been tested at the universities of Delft and Twente in the Netherlands and continues to be refined.[224] 'In addition to people who suffer from spinal cord injuries, the research could also eventually be used to assist the rehabilitation of stroke victims, and to help astronauts rebuild muscle mass after prolonged periods in space.'[225]

Other non-invasive neural interface devices that can sense and interpret peripheral EMG signals or potentials include a range of myoelectric prosthetics by Ottobock,[226] the Endolite Lynx,[227] Steeper's bionic hand that is now owned by Ottobock,[228] Mobius Bionics' LUKE Arm[229] and Touch Bionics' i-limb quantum myoelectric hand.[230]

(a) The DEKA or LUKE Arm

Touted as the bionic arm, the DEKA arm was developed by Dean Kamen of Segway and then DEKA Research & Development Corp, together with over 300 scientists, and was commissioned by the United States Defense Advanced Research Projects Agency (DARPA).[231] A remarkable attribute of this neuroprosthetic arm is that the person can,

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[223] Adam Williams, 'Mindwalker mind-controlled exoskeleton could help the disabled walk again' (14 March 2013) *New Atlas* <http://newatlas.com/mindwalker-mind-controlled-exoskeleton/26611/>.

[224] Alex Wang, *Mindwalker Exoskeleton Tests* (27 August 2015) YouTube <https://www.youtube.com/watch?v=F-mrSGhjybM>. The project developing Mindwalker, is expected to run for three years and has received a grant of EUR 2.75 million under the European Union's Seventh Framework Program (FP7).

[225] Williams, above n 223.

[226] Ottobock, *Myoelectric prosthetics* (2017) <http://www.ottobockus.com/prosthetics/upper-limb-prosthetics/solution-overview/myoelectric-prosthetics/index.html>.

[227] Endolite, *Lynx* (2018) <http://www.endolite.com/products/linx>.

[228] Ottobock, *Into the Future with Ottobock* (2018) <http://bebionic.com/>.

[229] Mobius Bionics, above n 121.

[230] Touch Bionics, *Touch Bionics* (2018) <http://www.touchbionics.com/products/i-limb-whole-hand-solutions>.

[231] IEEE, above n 124. See Figure 1.5 The LUKE Arm.

through the neural impulses from the brain (efferent) and signals sent to the brain (afferent), pick up a grape or raisin and know the difference without looking.[232]

In February 2008, the DEKA Arm was preparing for clinical trials[233] and then it was the first advanced, integrated prosthetic arm the Food and Drug Administration (FDA) approved for commercialisation.[234] It was reported that the device operated in the following way:

> Control of the fully functioning hand is directed by a patient's nervous system since the nerves that come from the spinal cord are still available in the shoulder. As an amputee simply thinks about moving their missing hand, the brain fires electrical impulses that are detected by electrodes in the prosthesis. So there is no real learning curve for the amputee. Additional control over the arm is generated by pressing buttons built into the patient's shoes. So the DEKA Arm both recognizes signals *from* the brain (efferent) and relays signals back *to* the brain (afferent).[235]

The DEKA arm is now trade marked as the LUKE (Life Under Kinetic Evolution) Arm[236] and is being sold by Mobius Bionics LLC.[237]

There are a range of input devices that will operate the LUKE arm:

> The LUKE arm has a very flexible control system that allows the arm to be controlled by a variety of input devices. Familiar input devices may be used such as surface EMG electrodes and pressure switches.[238] In addition, the LUKE arm may be controlled by intuitive wireless IMUs (inertial measurement units) that are typically worn on top of the shoes. The clinical team and the client work together to develop the input configuration that best meets the client's needs.[239]

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[232] Ibid.

[233] Sarah Adee, 'Dean Kamen's "Luke Arm" Prosthesis Readies for Clinical Trials: DARPA May Decide the Fate of Dean Kamen's Next-Generation Prosthetic Arm' (1 February 2008) *IEEE Spectrum* <http://spectrum.ieee.org/biomedical/bionics/dean-kamens-luke-arm-prosthesis-readies-for-clinical-trials>.

[234] Mobius Bionics, above n 121. Also see, Anon, above n 121 .

[235] IEEE, above n 124.

[236] Brendan McGarry, *Military Amputees May Soon Get 'LUKE' Bionic Arms* (4 January 2017) Military.com <https://www.military.com/defensetech/2017/01/04/military-amputees-may-soon-get-luke-bionic-arms?ESRC=deftech.sm>.

[237] Mobius Bionics, above n 121. Also see, Anon, above n 121.

[238] 'Surface EMG: A technique in which electrodes are placed on (not into) the skin overlying a muscle to detect the electrical activity of the muscle,' Anon, *Medical Definition of Surface EMG* (13 May 2016) MedicineNet <http://www.medicinenet.com/script/main/art.asp?articlekey=34020>.

[239] Mobius Bionics, above n 121.

3 *Combination of Neural Interface Devices*

BrainGate is an invasive neural interface brain implant that enables recipients to control a variety of assistive devices. The LUKE arm is a non-invasive neuroprosthetic arm that can be controlled by surface EMG electrodes or by wireless communication. Individually, they enable individuals to move from their physical or neurological limitations while together they may enable interaction with the world beyond the patient's expectations.

BrainGate and the DEKA arm were used in combination to enable a person to give herself a drink of coffee for the first time since becoming paralysed almost 15 years earlier.[240] As a result of the research conducted through to 2012, participants in the BrainGate2 pilot clinical trials with tetraplegia, were able to communicate with the LUKE arm through BrainGate to achieve three-dimensional reach and grasp movements of the LUKE arm.[241] One of the participants was able to control the LUKE arm 'to reach for and pick up a bottle of coffee, and then drink from it through a straw and place it back on the table'.[242] The research showed:

> That two people with no functional arm control due to brainstem stroke used the neuronal ensemble activity generated by intended arm and hand movements to make point-to-point reaches and grasps with a robotic arm across a natural human-arm workspace.[243]

Neural interface devices will enable those who have restricted movement capabilities to use assistive robotic devices to provide physical independence.[244] The neural interface devices discussed above are a small sample of the innovative research outcomes that are occurring. For the purposes of legal analysis, the technology upon which these devices operate is important.

[240] Hochberg et al, above n 119, 374.
[241] Ibid 372.
[242] Ibid 373.
[243] Ibid.
[244] Serruya and Donoghue, above n 64, 1158.

C Neural Interface Device Technology

> The possibility of an effective connection between neural tissue and computers has inspired scientists and engineers to develop new ways of controlling and obtaining information from the nervous system. These applications range from 'brain hacking' to neural control of artificial limbs with brain signals. Notwithstanding the significant advances in neural prosthetics in the last few decades and the success of some stimulation devices such as cochlear prosthesis, neurotechnology remains below its potential for restoring neural function in patients with nervous system disorders. One of the reasons for this limited impact can be found at the neural interface and close attention to the integration between electrodes and tissue should improve the possibility of successful outcomes.[245]

Neural interface technology to record neural activity has existed since the 1840s, 'since Du Bois-Reymond discovered the neural action potential more than 160 years ago,'[246] and has assisted in improving the treatment of neurological injuries and disorders.[247] It has enabled the development of the Hodgkin-Huxley model,[248] microwire-array technology[249] and micro-machined electrode-array technology.

> Other researchers were using electrodes to unlock the brains of monkeys. In one headline-grabbing experiment, Duke University's Miguel Nicolelis, connected the motor cortex of a rhesus monkey to a robot arm in the next room. Using only its thoughts, the animal harnessed the arm to play a simple video game. 'At that moment,' Nicolelis wrote, 'the cumulative years of research and the hopes of thousands of severely paralyzed people who dreamed of one day regaining some degree of their former mobility became deeply intertwined.[250]

To achieve a connection between the nervous system and the neural interface device, an understanding of the nervous system is required. Neural interface devices primarily interface with either the central nervous system or the peripheral nervous system. The central nervous system 'consists of the brain and spinal cord and is essentially the central processing unit

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[245] Dominique M Durand, 'Focus on the neural interface' (2009) 6 *Journal of Neural Engineering* 1, 1.

[246] Jack W Judy, 'Neural Interfaces for Upper-Limb Prosthesis Control' (2012) 3(2) *IEEE Pulse* 57, 58.

[247] Ibid.

[248] 'That describes how neural action potentials (or spikes) are generated and propagated' - Judy, above n 246, 58.

[249] 'Enabled the activity of neuronal populations to be observed and the movement of limbs to be decoded' - Judy, above n 246, 58.

[250] Gay, above n 8, 16.

for the body.'[251] The brainstem, that is located at the base of the brain, is responsible for controlling respiration and other basic functions.[252] 'Emotional response to stimuli, memory formation and temperature regulation' are controlled by the 'thalamus, hippocampus, basal ganglia and other deep structures,' which are located above the brainstem.[253]

In the lower back of the brain is the cerebellum that 'receives motor and sensory input and appears to be responsible for posture and motor coordination.'[254] On the surface of the brain is the cerebral cortex that consists of six layers and various domains, 'such as the visual cortex, auditory cortex, somatosensory cortex and motor cortex, primarily responsible for the initiation, execution, or processing of certain functions.'[255] The spinal cord carries both sensory and motor information involving interneurons and motor neurons that interact with a number of different cells within the central nervous system.[256] This interaction of cells is involved in neural interface devices.[257]

Many of the devices that interface with the central nervous system primarily use voluntary control of brain activity.[258] These 'are controlled by components of the electroencephalogram' including 'sensorimotor-rhythm (SMR) or μ-rhythm,' some of which are distinct brain rhythms directing hand and foot movement.[259] Interfacing with the central nervous system is now a major focus of neuroengineering research in an effort to correct or alleviate the symptoms of neurological dysfunction or to enable brain-computer interface.[260]

In *Neuroprosthetics: Theory and Practice*,[261] the authors provide an explanation of the complex anatomy and physiology of the central nervous system and the neurological basis upon which the brain can communicate, through the nervous system, with a neuroprosthesis or artificial body part. In this way, the authors capture the technical principles of neural

[251] Grill, Norman and Bellamkonda, above n 63, 10.
[252] Ibid.
[253] Ibid 10-11.
[254] Ibid.
[255] Ibid.
[256] Ibid.
[257] Ibid.
[258] S Halder et al, 'Neural Mechanisms of Brain–Computer Interface Control' (2011) 55 *NeuroImage* 1779, 1779.
[259] Ibid 1779-1780.
[260] Grill, Norman and Bellamkonda, above n 63, 9.
[261] Kenneth W Horch and Gurpreet S Dhillon (eds), *Neuroprothetics: Theory and Practice* (World Scientific Publishing Co, 2004).

interface devices that enable the development of many different devices. These included cochlear implants, deep brain stimulation and neuromotor prostheses. In relation to neuromotor prosthetic devices, Mijail Serruya and John Donoghue provided a detailed analysis of the design principles.[262] The general technical principles are as follows:

> NMP [Neuromotor prostheses] are a type of BMI [brain-machine interface] that seek to extract signals from the central or peripheral nervous system and deliver them to control devices. A brain-machine interface is necessary to detect activity that can be voluntarily modulated for use as a motor control signal. It is generally accepted that electrical potentials are the most valuable sources of information. Neural commands for voluntary movement are essentially issued as electrical signals produced by the spiking (action potentials) and synaptic input of individual neurons; both can be recorded with varying degrees of fidelity and difficulty. The goal is to be able to detect signals that have the largest amount of information about movement and that change about as rapidly as movement commands themselves change. Clearly, recording at the source of the motor commands most readily fulfils these requirements, but indirect recordings of surrogate signals can provide an alternative or supplemental source, if one can learn to make indirect signals mimic motor commands. The decoding methods for use in neuromotor prostheses are the culmination of many years of basic research on the motor system. Whereas recovering movement dynamics and kinematics from neural activity alone comprises a feat of basic science, their use as a control signal marks a shift to applied neuroprosthetics.
>
> Three overarching components are necessary for any NMP. First, an interface with the nervous system must be developed. This brain machine interface must provide a means to detect or inject signals, be safe, last for long periods of time. The interface may contain only passive components, but active signal processing may be required for weak or noisy electrical signals. For devices that are implanted into the body, both the interface and attached processing units must be biocompatible, immune to tissue damage, and sufficiently compact to fit into or onto the body.
>
> The second essential design component is signal decoding. Once signals are acquired, subsequent instrumentation must further process signals into a form appropriate for

[262] Serruya and Donoghue, above n 64, 1158. The ebook can be accessed at <https://books.google.com.au/books?id=9dDUCgAAQBAJ&pg=PA1158&lpg=PA1158&dq=design+principles+of+a+neuromotor+prosthetic+device&source=bl&ots=eF0eZckiHG&sig=rTr4eGgInyuYSEtspkiz6l5XnMs&hl=en&sa=X&ved=0ahUKEwipjYG24a_RAhVLFpQKHR8PDSAQ6AEILDAD#v=onepage&q=design%20principles%20of%20a%20neuromotor%20prosthetic%20device&f=false> and this chapter is available online at <https://www.researchgate.net/publication/242388973_Design_Principles_of_a_Neuromotor_Prosthetic_Device>.

> mathematically-based decoding algorithms. The output of the second processing stage is in a form that can be used by physical or biological devices that produce intended actions. In a sense this component is a decoder that translates brain language into machine language.
>
> The third component required for an NMP are devices that make effective use of the neural control signals. This includes not only the identification of devices that serve practical purposes, but also the engineering of interfaces that can allow safe, meaningful use of the control signals. Such devices include computer point-and-click type interfaces, the person's own muscles, robotic arms, or even semiautonomous robots.[263]

Grill, Norman and Bellamkonda also provided insight into the science and technology underlying both implanted and peripheral neural interfaces.[264] In relation to communication with the nervous system, electrical stimulation can put information into the nervous system while recording of neural activity provides information.[265] In this way, the central nervous system, comprising of the brain and spinal cord, can communicate with the periphery nervous system which receives and outlays information to muscles and joints.[266]

Neural interface sensors can be either intracortical[267] or extracortical[268] and provide the source signal to the neural interface system incorporating a neural interface device.[269] Intracortical sensors are invasive neural interface sensors that are in direct contact with the functional parts of the human body, such as the brain or central nervous system. Extracortical sensors are non-invasive neural interface sensors that are in contact with external parts of the human body, such as the skull or the skin. As a result, the intracortical neural interface sensors are able to record a greater range of neural signals than extracortical sensors.[270] Neural recording has enabled 'the study of coding properties of peripheral sensory neuron and the recovery of nerve population activity for command and feedback signals to control prosthetic devices.'[271]

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[263] Ibid 1158-1159.

[264] Grill, Norman and Bellamkonda, above n 63.

[265] Ibid 2-3.

[266] Ibid 2.

[267] In direct contact with cortical parenchyma, in very close proximity to neurons. Donoghue et al, above n 155, 604.

[268] In direct contact with extracortical tissues, such as the skull and skin. Donoghue et al, above n 155, 605.

[269] Donoghue et al, above n 155, 604.

[270] Ibid.

[271] Grill, Norman and Bellamkonda, above n 63, 3.

The mechanism that decodes the neural impulse and then instructs the assistive device to operate as intended is different from the neural sensor and is a complicated part of the neural interface device. The decoder may or may not be located in close proximity to the neural sensor but its proximity to the neural impulses does not impact on the accuracy of the decoding. It is the location of the neural sensor that determines the strength of the neural impulse received. Research has been undertaken in relation to point-and-click computer cursor control with an intracortical neural interface system.[272] 'A key component of this system is a multi-state probabilistic decoding algorithm that simultaneously decodes neural spiking activity of a small population of neurons and outputs either a click signal or the velocity of the cursor.'[273] To achieve some appreciation of the complexity of the mathematical computations and modelling required to be performed by the decoder to enable this, see Appendix 2.1.[274]

Despite the complexity of neural interface systems, research has enabled neural impulses to be decoded to instruct an assistive device, whether that be a computer cursor or other assistive device.[275] Research in the field is being undertaken throughout the world.[276] The sale of neural interface devices for use by consumers will be well controlled by government entities. In the United States, it is the Food and Drug Administration (FDA) and in Australia

[272] Kim et al, above n 177.

[273] Ibid 193.

[274] Appendix 2.1 provides a segment of a decoding model employed in a neural interface device.

[275] Ibid.

[276] For example, an international project known as The Virtual Brain is a computer program that simulates the human brain and is use by medical practitioners, neuroscientists and researchers. Williams, above n 223; Semeniuk, above n 157, A11; The Virtual Brain Foundation, *The Virtual Brain* <http://www.thevirtualbrain.org/tvb/zwei>; The Virtual Brain Foundation, *Download the Virtual Brain for Free* <http://www.thevirtualbrain.org/tvb/zwei/brainsimulator-software>.

In the United States, the National Institutes of Health (NIH) funds research in this area and in 2016 grants totaled more than $US150 million included funding in next generation human invasive devices, non-invasive neuromodulation and understanding neural circuits. US Department of Health and Human Services, *The BRAIN Initiative* (11 April 2018) <https://www.braininitiative.nih.gov/>; National Institutes of Health, *BRAIN 2025: A Scientific Vision* (5 June 2014) <https://www.braininitiative.nih.gov/pdf/BRAIN2025_508C.pdf>; National Institutes of Health, *What is the BRAIN Initiative?* <https://www.braininitiative.nih.gov/>; <https://braininitiative.nih.gov/funding/fundedAwards.htm>.

Some of the research being undertaken in the United States includes:

The Athinoula A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital is researching advanced biomedical imaging technologies: Harvard University, *Athinoula A. Martinos Center for Biomedical Imaging*, <http://www.nmr.mgh.harvard.edu/about/overview>.

In Australia, interdisciplinary collaborative research on the brain is being undertaken at the Brain and Mind Research Institute at the University of Sydney: University of Sydney, *Brain and Mind Centre* <https://sydney.edu.au/brain-mind/>; and the at Queensland Brain Institute: The University of Queensland, *Queensland Brain Institute* <http://www.qbi.uq.edu.au/>.

it is the TGA[277] who are responsible for accreditation of medical devices including neural interface devices. The application of existing certification processes to accreditation of neural interface devices is discussed in chapter 5.

D *Limitations of Neural Interface Device Technology*

Despite the advances made in neurotechnology with the development of neural interface devices, there remain many opportunities for improving the neural interface components, decoding of neural impulses and knowledge of how the brain functions. Brain-computer interface still has a long way to progress before it can 'rival the elegance and diversity of biological movement.'[278] 'However, the underlying principles also create fundamental biophysical and biological challenges.'[279] The following identify some of the limitations of neural interface device technology.

1 *Unreliability*

Whilst neurons have been accessed for information, they can also be unreliable.[280] The mechanical network and mechanical waves that move along nerves and play a role in communication from the brain are so small, 10 micrometres,[281] that there exists difficulty in researching the phenomenon.[282] This presents interfacing challenges for the technology. One of the challenges involves 'the ability to collect signals from and send stimulation to a portion of the neuron-dense brain.'[283]

> The brain carries information that has regional specificity to certain functional areas, and yet sometimes this information may be coordinated over distances that are large relative to implant size; it is against this background that we are presented with the trade-off between invasiveness and spatial resolution. The application of a neural interface will typically dictate

[277] Australian Government, *Australian Government, Department of Health, Thereupeutic Goods Administration* (2018) <http://www.tga.gov.au/>.

[278] Gay, above n 8, 16.

[279] Grill, Norman and Bellamkonda, above n 63, 3.

[280] Gay, above n 8, 16.

[281] 'A "micron" is an abbreviated term for "micrometer", or a millionth of a meter (1/1,000,000 meters). For size comparison, 'a human red blood cell is about 5 microns across. A human hair is about 75 microns across (depending on the person).' Anon, *How Big is a Micron* <http://www.bacteria-world.com/how-big-micron.htm>.

[282] Anil Ananthaswamy, 'Like Clockwork' 219 (2932) *New Scientist* 33, 34.

[283] Grill, Norman and Bellamkonda, above n 63, 10.

what level of invasion can be tolerated and what level of spatial resolution will be required to achieve a given goal.[284]

The complexity of decoding the neural impulses results in a degree of inaccuracy. In addition, communication from the assistive device to the brain may also be less than 100 per cent accurate, which contributes to a degree of unreliability. This will impact on the application of current law and the certainty of evidence, which is discussed in the following chapters.

2 *Instability and Poor Biocompatibility of the Neural Sensor*

The brain, like the rest of the body, 'abhors foreign objects, and while the platinum sensors create a close union between mind and machine, it may often be short-lived.'[285] The main reasons for instability and poor biocompatibility of invasive neural sensors are 'failure of the encapsulation material after 3-12 months, destruction of the surrounding nerve tissue through collateral damage from a thin microphage layer on the implant and immune system reactions to wires and connectors.'[286] Weak signals and recording failure may also be caused by inflammation and gliosis surrounding the neural interface.[287] In addition, the restoration of sensory damage to the area around the implant is yet to be resolved.[288]

[284] Ibid.

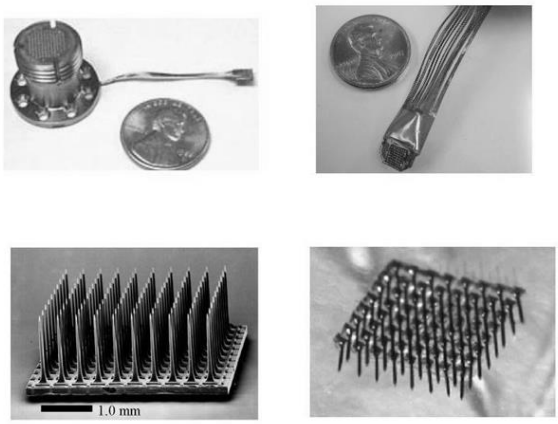
[285] Gay, above n 8, 16.

[286] F Solzbacher et al, 'Integrated Neural Interfaces Arrays for Neuroprosthetics Applications' (2005) 1(3) *Nanomedicine: Nanotechnology, Biology, and Medicine* 250, 250-1.

[287] Grill, Norman and Bellamkonda, above n 63, 10. The authors cite the following in support of this statement: JN Turner et al, 'Cerebral astrocyte response to micromachined silicon implants' (1999) 156(1) *Experimental Neurology* 33.

[288] Durand, above n 245.

Figure 2.3 Multi-Electrode Array Technology



Two examples of multi-electrode array technology that can be implanted on the cortex of the brain, the central nervous system and the peripheral nervous system and sense neural impulse, are provided in Figure 2.2. Developed by Dr Richard Normann at the University of Utah, the Utah array is pictured in the lower left photo while the array can be seen at the upper left with a connector and wires in the photo above.[289] The lower right photo shows a metal array developed collaboratively by MIT and Brown University.[290] The upper right photo shows the array, connector and wires.[291]

'One problem with implanted electrode arrays, however, is that they can fail to record reliably neural signals for long periods of time. Another problem with the neural interface is the mismatch of the mechanical properties between electrode and tissue.'[292] In addition, implanted electrodes move. 'For example, an electrode for a prosthetic forearm implanted in the vestigial limb can be jolted away from its target neuron by sudden body movements.'[293] Brain implants are also vulnerable to movement primarily as fibrous tissue grows around them.[294] However, BrainGate has been able to survive for more than five years after implantation[295] so longevity is being improved as researchers and engineers craft highly

[289] Serruya and Donoghue, above n 64, 1158. Bionic Technologies (now part of Cyberkinetics, Inc) commercialised the Utah array.

[290] Ibid.

[291] Ibid. See also Dr Normann describing how the Utah array operates: Richard Normann, 'Utah Electrode Array' (Speech delivered for the University of Utah Neuroscience Initiative at The Brain Institute, University of Utah, 27 February 2012) <https://www.youtube.com/watch?v=ItI6PqSTdHQ>.

[292] Durand, above n 245.

[293] Graham-Rowe, above n 197, 30.

[294] Ibid.

[295] Hochberg et al, above n 119, 372.

sensitive, accurate interface that will not degrade over time.[296] Instability and poor biocompatibility of neural sensors impact on the accuracy of neural recording which will hamper the operation of the neural interface device. Critically, this will impact on the application of the current law with regard to negligence and manufacturer liability, an analysis of which is undertaken in chapters 4 and 5, respectively.

3 *Inaccurate Recording and Decoding of Neural Impulses*

Neural sensors placed on the outer part of the human body, such as EEG, provide:

> Only a hazy portrait of the electrical storm raging inside the skull. Placed directly on the scalp, EEG electrodes cannot always differentiate between the electricity inside the brain and the electrical pulses that animate the scalp. It leads to a muddy signal, adulterated with muscular electricity and even surrounding electronics.[297]

The integration between electrodes and tissue is critical to ensure the success of the neurotechnology, otherwise the neural interface device will have limited impact in achieving successful outcomes.[298] As electrodes connect to many cells it is difficult to target a signal without receiving or creating interference.[299] Limited knowledge of brain function also plays a role in the recording and decoding of neural impulse accuracy.

> The neural matrix is wildly complex. We understand very little of even the brain's most basic functioning, and its three pounds of neural tissue do not readily yield their secrets to the system of 1s and 0s Leuthardt and his cohorts would use to reveal its mysteries. And that's to say nothing of the more basic biological problem researchers encounter when they try to join the hard stuff of electrodes to the squishy tissue of the brain.[300]

> The goal of advanced neural-recording interfaces has been to support fundamental neuroscience activities, such as understanding how functions of interest are encoded in various neural signals [e.g., single-unit activity, multiunit activity, local field potentials (LFPs), and brain-wave activity]. However, since scientific experiments performed to date have

[296] Gay, above n 8, 17; Solzbacher et al, above n 286, 250-1.
[297] Gay, above n 8, 17.
[298] Durand, above n 288, 1.
[299] Graham-Rowe, above n 293, 30.
[300] Gay, above n 8, 22.

> typically been short term (i.e., on the order of months to a year or two), the emphasis of engineering activities supporting this work has not been directed toward improving the long-term reliability of neural-interface systems, but rather the development of real time data acquisition and processing systems. As a result, it is not surprising that technologies presently used for neural interfaces have demonstrated an inability to maintain a consistently high level of performance for very chronic time periods in healthy and active animal models up to and including nonhuman primates.[301]

Cognitive computing, that might become part of the neural interface system, is not yet as powerful as the human brain. Jerome Pesenti, the lead developer of IBM Watson which operates on cognitive computing, acknowledged that the human brain is 100,000 times more powerful than the current cognitive computer capacity. On 2 December 2014, Pesenti estimated it will take up to 25 years before computers will operate as powerfully as the human brain.[302] Cognitive computing, involving machine learning, will be used in the decoder where decoding algorithms not only interpret neural impulse but also instruct the assistive device.[303] Machine learning and cognitive computing will enable the decoder to become more accurate over time but the ability for computer scientists to know exactly what the decoder has done will impact on the available evidence in civil disputes.

Combined with the technical shortcomings of neural sensors and decoders and limited understanding of the functioning of the brain means neural interface devices are imperfect. When developing the technology, careful consideration of patient acceptance of the shortcomings and error rates should occur. 'Unless appropriate functional targets are set beforehand much time, money, and effort could be wasted, and many more patients will go through life without enjoying the envisioned benefits.'[304] Product accreditation by Australia's TGA will determine the acceptable error rates. This is discussed in chapter 5 together with the required product disclosure requirements.

[301] Judy, above n 246, 58.

[302] Pesenti, above n 137, 13:27–16:33 minutes.

[303] Kim et al, above n 177, 193.

[304] Judy, above n 246**Error! Bookmark not defined.**, 58-9.

4 *Neural Interface Power Needs are Challenging*

Implantable neural interface devices are becoming a key enabling technology.[305] This technology requires:

> Extremely low power, small, low noise, highly parallel, and distributed electronic microsystems, which interface with the brain using biocompatible microelectrode arrays to provide high cell yield recordings, large channel counts and access to spike data and/or field potentials with high signal-to-noise ratio (SNR). The system constraints impose strict limitations on size and power dissipation, requiring highly integrated approaches, and the allocation of signal processing and computational resources, in both analog and digital domains, to maximize efficiency across all major hardware components such as analog signal conditioning, digital signal processing and wireless communication circuits.[306]

The complex powering requirements for neural sensors that are implanted is of high importance and researchers are seeking to develop devices that require extremely low power.[307] Shortcomings that might arise in the powering of neural interface device will play a role in determining liability for resulting accidents. This is discussed in chapters 4 and 5.

5 *Appropriate Application and Use of Neuroscientific Research Outcomes*

Research being undertaken to discover how the brain functions will make an impact on the correct operation of neural interface devices and overcome some of the shortcomings. This will impact on the decoding of neural impulse and the communication between the neural interface device and the brain. There is a danger, however, that conclusions drawn by the researchers from the outcomes of neuroscientific research go beyond what is validly supported by the results.[308] For this reason, care in accepting the conclusions drawn by researchers must be exercised by those involved in the development of neural interface devices. The research outcomes will also impact on the ethical and just decisions in the legal system. The resources provided by organisations such as the Massachusetts General

[305] Chung-Ching Peng, Zhiming Xiao and Rizwan Bashirullah, 'Toward Energy Efficient Neural Interfaces' (2009) 56(11) *IEEE Transactions on Biomedical Engineering* 2697, 2697.

[306] Ibid.

[307] Ibid.

[308] Sally Satel and Scott Lilienfeld, *Brainwashed: The Seductive Appeal of Mindless Neuroscience* (Basic Books, 2013).

Hospital Center for Law, Brain, and Behavior assist lawyers and judges in understanding neuroscience and its application to the law,[309] reinforcing the appropriate use, by the legal profession, of these neuroscience research outcomes. Neuroscience and the law, including neurolaw and neuroscientific evidence, are discussed further in chapter 6.

E *Summary*

Neural interface systems encompass sophisticated technology that enables integration of machine with the human brain and body. The complexity of the brain and neural system is so great that full understanding of how these work is still being discovered through neuroscientific research. Interfacing with the human brain and neural system is far from perfect so the ways in which they work and the limitations of neural interface devices must be recognised when a dispute comes before a court of law. To identify these limitations, this chapter has introduced the technical principles upon which neural interface devices operate and current parameters of operation. Many issues will flow from the melding of mind and machine through neural interface devices and some are identified throughout this thesis. This chapter provides the technical basis for analysis in chapters 3, 4 and 5, leading to recommendations and conclusions in chapter 6. Chapter 3 provides the outcomes of Delphi Method Research involving legal experts who identified legal issues and the impact of neural interface devices on the law.

> Neuroprosthetic devices, or brain-machine interfaces, will also allow scientists to do much more than help the disabled. They will make it possible to explore the world in revolutionary ways by providing healthy human beings with the ability to augment their sensory and motor skills. In this futuristic scenario, voluntary electrical brain waves, the biological alphabet that underlies human thinking, will manoeuvre large and small robots remotely, control airships from afar, and perhaps even allow the sharing of thoughts and sensations of one individual with another over what will become the collective brain-based network.[310]

Nicolelis believes that 'eventually, brain implants will become as common as heart implants'.[311] As a result of neural interface devices that augment human ability, Eric

[309] Massachusetts General Hospital, *Massachusetts General Hospital Center for Law, Brain & Behavior* (2012) <http://clbb.mgh.harvard.edu/>.

[310] Nicolelis, above n 131, 44-6.

[311] Zimmer, above n 160, 56.

Leuthardt believes that '[e]ssentially, you've unleashed the brain on the world'[312] and civil liability challenges for the law will inevitably occur. The remainder of this thesis analyses these challenges.

[312] Gay, above n 8, 25.

III CHAPTER 3 LEGAL ANALYSIS USING THE DELPHI METHOD

A *Introduction – The Delphi Method*

Recognising the medical advances in neural interface devices described in chapter 2, original research using the Delphi Method was undertaken where Australian legal experts identified the civil legal issues that will arise and how the law would and should address these issues. These legal experts included Judges of Supreme Courts, Queen's Counsel, Partners and Special Counsel of top tier law firms and university law academics throughout Australia. This chapter provides the methodology and outcomes of this research. The Delphi Method was used as a qualitative technique to predict legal issues that will potentially arise and the possible solutions to those issues in the context of civil proceedings where there is a combination of human being and neural interface device with the functionality outlined in Figure 2.2 Neural Interface System. Analysis and discussion were conducted within the context of the Australian law and the research questions asked in the Delphi Method research test the research hypothesis.[313]

1 *The Delphi Method*

The Delphi Method was developed in the 1950s by Norman Dalkey of the Rand Corporation.[314] It is a method of eliciting and refining the judgments of experts and is particularly valuable in more accurately predicting future concepts, paradigms and strategies.[315] As the application of civil legal liability principles to a person with neural interface device has yet to arise in the courts, forecasting by legal experts was an essential and valuable tool in the research of the hypothesis.

There were a number of reasons for choosing to use the Delphi Method for this research. The analysis of legal issues in the context of future proceedings does not 'lend itself to precise analytical techniques but can benefit from subjective judgments on a collective basis.'[316] The participants selected were legal experts from the judiciary, the legal profession and universities throughout Australia. They were unlikely to be communicating with each

[313] See chapter 1 under the heading '*1* The Hypothesis'.
[314] Skulmoski and Hartman, above n 51, 2.
[315] Linstone and Turoff, above n 50, v.
[316] Ibid 4.

other on the research question and their perspectives would possibly be different. Each group would have a specific view point and may yield different perspectives. Qualitative research, unlike quantitative research that seeks at statistical overview from a large sample, seeks a depth of understanding from a small sample.[317]

Bringing these participants together to discuss the research question face-to-face would have been extremely difficult to achieve, so the Delphi Method research instrument was developed and used to enable collaborative engagement in addressing the complexity of neural interface devices and the law.

> The Delphi technique is an innovative way to involve busy experts and specialists who may not be able to come together to brainstorm, but who nevertheless need to interact with each other to generate new ideas.[318]

The number of participants was difficult to anticipate and preserving the heterogeneity and anonymity of the participants was of major importance to assure validity of the results, that is, 'avoidance of domination by quantity or by strength of personality ("bandwagon effect").' [319] The advantage of having expert judgment is the ability to more accurately predict the legal issues that could arise from the tightly confined facts of a future event.[320]

2 *The Delphi Method Research Conducted*

For these reasons, the Delphi Method research was evaluated as the optimum method for the purposes of this thesis. The typical Delphi methodology used by Skulmoski and Hartman is outlined in Figure 3.1 below, however, the process can be modified to address the research questions.[321]

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[317] Leavy, above n 15, 9.

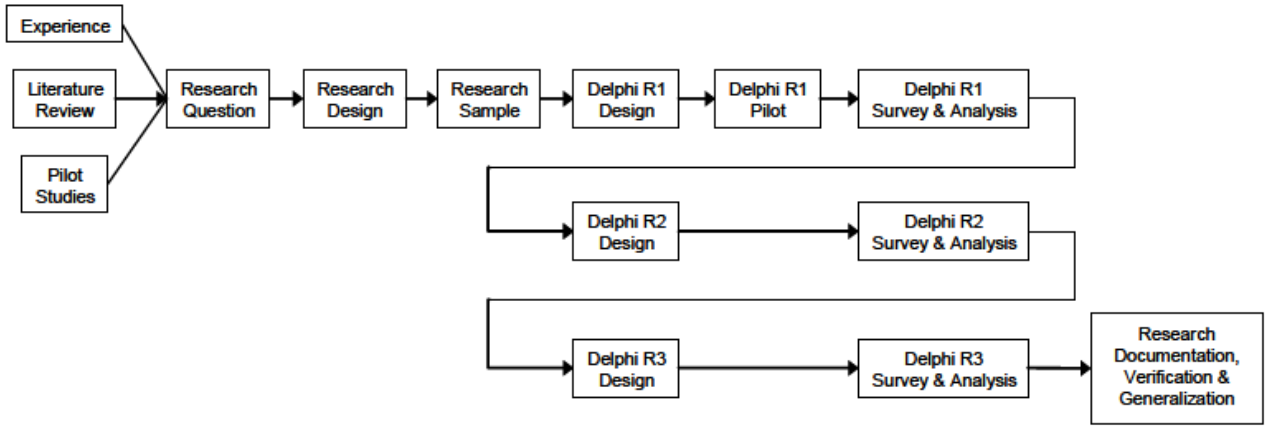
[318] James M. Nehiley, *How to Conduct a Delphi Study' in Victorian Department of Sustainability and Environment, 'Delphi Study'* <http://www.dse.vic.gov.au/effective-engagement/toolkit/tool-delphi-study>.

[319] Ibid.

[320] David McDonald, Gabriele Bammer and Peter Deane, *Research Integration Using Dialogue Methods*, (ANU E Press, 2009) 49.

[321] Skulmoski and Hartman, above n 51, 5.

Figure 3.1 Three Round Delphi Process[322]



While the number of rounds is often three, one or two rounds have been used and the number of participants has ranged throughout research projects from 8 to 345.[323] Two rounds were conducted and of the twenty-seven legal experts who had agreed to participate in the research, three members of the judiciary, four legal practitioners and five law academics provided responses to the Rounds 1 and 2 questions.

The Delphi Method, based on the typical Delphi methodology used by Skulmoski and Hartman,[324] was the basis for the research undertaken. The steps conducted were the following:

1) Development of the Research Question. This was undertaken and examined in relation to the research hypothesis.[325]

2) Designing the Research – The Delphi Method was used to collect the judgments and opinions of legal experts in the judiciary, legal profession and university law academia. The research questions included in the Delphi Method research were derived from the literature review and conceptual analysis of the research hypothesis.

[322] Ibid 3.

[323] Ibid 5 and 9.

[324] Ibid 3-5.

[325] The research hypothesis is stated above under the heading '*1* The Hypothesis'.

3) Research Sample – The selection of research participants was determined using the four requirements for 'expertise':

    i) Knowledge and experience with the issues under investigation;
    ii) Capacity and willingness to participate;
    iii) Sufficient time to participate in the Delphi Method research; and
    iv) Effective communication skills.[326]

4) The Stimulus – The stimulus was developed and tightly defined to provide the information to participants. This ensured that the respondents understood the research questions to accurately address the issues examined and to ensure that sufficient information was provided. The stimulus dealt explicitly with the factual boundaries within which the legal issues were sought and a copy is available in Appendix 3.2.

5) Delphi Preliminary Studies –

    - *Pre-test of the Stimulus*. A study, including interviews, was undertaken to refine the stimulus, improving comprehension and removing ambiguity, misinterpretation and misunderstanding. A copy of the amendments to the stimulus is available in Appendix 3.1.

    - *Pilot of online research instrument*. This was conducted to remove technical and procedural problems with the operation of the online research instrument.

6) Release Round 1 Research Instrument and Analyse Responses - The access to the online research instrument enabled the participants to complete Round 1 of the study. Participants were asked to identify and describe the legal issues they believe would arise in civil proceedings based on the information in the stimulus. Participants were also asked to identify how the law might respond and deal with these issues. The

[326] Erio Ziglio, 'The Delphi Method and its Contribution to Decision-Making' in Michael Adler and Erio Ziglio, *Gazing into the Oracle: The Delphi Method and its Application to Social Policy and Public Health* (Jessica Kingsley Publishers, 1996) 3, 14. Ziglio acknowledges on this page that 'the definition of "experts" varies according to the context and field of interest in which the Delphi Method is going to be applied. Being an expert entails the acquisition of experience, special skill in or knowledge of a particular subject.'

responses of Round 1 were then summarised and this summary is available in Appendix 3.6.

7) Development of Round 2 Research Instrument - The Round 2 research instrument was based on the Round 1 responses.

8) Release Round 2 Research Instrument and Analyse Responses – Access to the research instrument was given to the Delphi Method research participants. The participants were provided with the opportunity to reflect on the legal issues identified by all participants in Round 1 and then allocate a level of importance to each of the issues. Participants were asked to provide reasons for the ranking allocated and then identify how the law would address the legal issues. Responses received in Rounds 1 and 2 are available in Appendix 3.7.

9) Document Research Results - The Delphi Method research results were compiled for analysis to allow for quantitative analysis of the data.

In summary, the development of the information (stimulus) provided to participants ensured the legal experts understood the research questions sufficiently to accurately address the issues. In Round 1 of the Delphi Method research, participants were provided with the stimulus and asked specific questions. The participants gave answers to those questions and identified the legal issues that would arise. The participants also evaluated how the current law would resolve the legal issues they had identified. In Round 2, participants were provided with all the legal issues identified by the participants in Round 1 and they allocated a value of importance to each of the legal issues.

B *Pre-test of the Stimulus*

The Pre-test was designed to enable identification of any potential misinterpretation or misunderstanding of the statements made in the stimulus. This was important as the stimulus contained all the information regarding the type of neural interface device that would be the basis upon which participants in Rounds 1[327] and 2[328] would answer the

[327] Round 1 of the study was conducted to facilitate the identification and description of legal issues based on the research issue defined in the stimulus. Participants were also asked to suggest how the law might address these issues.

[328] Round 2 provided participants with the list of issues that had been identified by participants in Round 1 and all participants were asked to:

research questions. The stimulus was provided to each of the participants in the Pre-test prior to an interview. The stimulus provided parameters to limit the scope of the research so that all participants would be working from the same information.

1 *Pre-test Interviews*

The Pre-test involved interviewing ten participants who would not be involved in any other part of the Delphi Method research. None of these participants provided responses in Rounds 1 and 2 of the Delphi Method research. Alreck and Settle outline the effectiveness of interviews stressing the need to:

- Locate;
- Identify;
- Contact;
- Greet;
- Qualify;
- Interrogate;
- Record; and
- Terminate.[329]

These aspects were considered in preparation of the interviews to ensure consistency throughout. In the Pre-test a convenience sample of participants were provided with the stimulus. These participants were chosen from the group of participants to be targeted for the online research instruments in Rounds 1 and 2, that is, legal academics, legal practitioners and members of the judiciary. They participated in the interview where questions were asked to determine their understanding of the material contained within the stimulus. They were also asked about the legal issues that they considered may arise in the area of the neural interface devices as outlined in the stimulus. Confidence intervals and a

- Allocate a level of importance to each of the issues;
- Provide reasons for their ranking;
- Discuss steps the participant believed might be required in order to address each of the legal issues; and
- Provide any further insight or clarification to the responses they had made in Round 1.

[329] Pamela L Alreck and Robert B Settle, *The Survey Research Handbook* (McGraw-Hill, 3rd edition, 2004), 225.

degree of sampling errors were not calculated for the Pre-test as these would have been technically invalid because the convenience sampling deviated from random sampling.[330]

The interviews presented an opportunity to obtain more information on the participants' understanding of the stimulus. However, it was important to ensure that consistency of both the questions asked and interaction between the researcher and the participant was maintained. This was to ensure that random error and systemic bias would be minimal so that the information obtained would be reliable and valid.[331] Elements of this consistency included the same interviewer undertaking all of the interviews, digital recording of each interview and exactly the same questions in the same order were asked of each of the participants.

In preparing for the interviews it was noted that there are 'few standard rules or common mythological conventions in qualitative research communities' and there is little guidance in relation to questions of the method such as sample sizes, formulation of questions, coding of answers and statistical methods of analysis.[332] Indeed, 'there is no common procedure for interview research' so it was determined that the following steps would be undertaken:

1. The Pre-test involved interviewing ten participants. Each of the participants were provided with a copy of the stimulus, information sheet and consent form prior to the time of interview to enable them to read and fully understand the interview process. Copies of the information sheet and consent form are available in Appendix 3.3. In relation to the wording of the stimulus, see step 5 below. The information sheet provided participants with the objectives of the Pre-test, how the study would be conducted and the security measures to protect anonymity. The consent form provided the researcher with each participant's express consent to participate in the Pre-test.

2. There were no formal introductory statements prior to the first question being asked, except to ensure that participants had read the stimulus and they were asked to sign the consent form.

[330] Ibid 43.

[331] Ibid 213.

[332] Steinar Kvale, *InterViews* (Sage, 1995), 12-13.

3. The same questions, see below, were asked in the same order and no additional questions were asked unless clarification of the answer provided by the participant was needed.

4. Written transcripts were produced from the recorded interviews.

5. Following the first five participants, amendments to the original stimulus were undertaken where there appeared to be a common misunderstanding or recommendation of change and this amended stimulus was the basis of the five interviews that followed, bringing the total number of participants to ten. A copy of the amended stimulus is available in Appendix 3.1 and the final stimulus in Appendix 3.2.

6. NVivo software[333] was used in an attempt to evaluate, interpret and explain participant responses. NVivo was excellent for this purpose because the software does not favour a particular methodology[334] and is designed to organise, analyse and find insights in unstructured, or qualitative, data such as the interviews conducted in the Pre-test.[335]

The following questions were asked of each participant:

1. Using your own words, can you tell me what this study is about?
2. Is there anything which is unclear about the description?
3. Do you have any other questions about these neural interface devices?
4. In what ways do you consider that these neural interface devices may lead to civil liability?
5. What legal issues will arise through the use of such devices?
6. How will the law resolve these issues?
7. What legal principles will be involved?
8. How can I improve the statement of the research issue?
9. Is there any other information you would like to have in developing your answers to the legal issues?

[333] QSR International Pty Ltd, *What is NVivo?* <http://www.qsrinternational.com/what-is-nvivo>.

[334] QSR International Pty Ltd, *NVIVO10: Getting Started* (QSR International Pty Ltd, 2013), 5.

[335] QSR International Pty Ltd, *Look through different lenses* <http://www.qsrinternational.com/nvivo/what-is-nvivo>.

10. Are there any other legal issues related to the use of these devices which would be of interest?
11. Are there any other comments you would like to share with me?

The interviews were conducted as a professional exchange rather than casual dialogue[336] so systematic questioning technique was used with critical attention to what was said. One-sided questioning of the participants occurred rather than discourse between the interviewer and the participant to resemble the online research instruments that were created for Rounds 1 and 2. The interviews sought an understanding of the participants' comprehension of the stimulus as well as the application of their legal knowledge to the research theme embodied in the stimulus. In this way, the interview was strictly structured with standardised questions so as to better predict the ways in which participants in the online research instruments for Rounds 1 and 2 would respond.

Every effort was made to avoid random errors,[337] such as instruction error or interpretation error. It was important for the participants to have time to read and consider this stimulus information in order to contemplate the legal issues that may be involved.

The interviews were conducted between 9am and 9pm, Monday through Friday, at locations in which the participants were comfortable and averaged 12 minutes per interview. This location was primarily at the participant's workplace and this facilitated accurate interrogation and recording. If an interview was interrupted by a telephone call or another person, the question the participant was answering before the interruption was repeated to ensure continuity.

In analysing the interview data, it was important to recognise that the responses were to be regarded as 'actively constructed narratives involving activities which themselves demand analysis' because the information provided in the stimulus involved a situation which is yet to come before the courts.[338] The participants' experience in the practice of law was inevitably captured in their responses. The NVivo software provided the ability to work directly with the text of the transcriptions preserving the context in which the material was taken. It also enabled code words and context to be identified automatically. The NVivo

[336] Kvale, above n 332, 19.
[337] Alreck and Settle, above n 329, 229-231.
[338] David Silverman, *Doing Qualitative Research* (Sage, 2000) 36.

coding technique was used to allow for the identification of some specific characteristics of the data. 'NVivo coding uses words or short phrases from the participant's own language in the data record as codes.' [339] This enabled the matching of responses to specific topics. The topics chosen for the coding of responses were:

- Shortcomings in the stimulus.
- Specific legal causes of action.
- The need to clarify or confirm the focus of the research in civil liability, not criminal.
- Additional material or formatting in the stimulus that would clarify the information.

The outcome of this coding of participant responses enabled identification of the required amendments to the stimulus, as provided in Table 3.1.

Table 3.1 Analysis of Responses from the First Five Pre-Test Participants

Change Suggested by Pre-test Participant	Change made to the Stimulus
Participant 1	
Use headings - the car example needs a heading to lead into this to clarify where it's going.	Headings inserted to better indicate the information contained throughout the stimulus.
The limits of the liabilities that arise, for example, criminal, civil, product liability etc.	Definition included in the research issue to explain the breadth of the term 'civil liability'.
Knowing whether the NID are homogeneous, do they work the same way, the same brain interface.	Heading and paragraph inserted to clarify the types of neural interface devices that are not included in the research.
Failure of device mentioned.	Heading inserted to make it clear that malfunction is not to be considered.
Clear statement of the research question, that is, here is the research question I am addressing. Examples are good, but in the end a clear statement of what I'm looking for needs to be stated.	Headings inserted at the beginning and before the last paragraph that make it clear what the research issue/question is looking for.

[339] Matthew B Miles, A M Huberman and Johnny Saldaña, *Qualitative Data Analysis: A Methods Sourcebook* (Sage, 3rd edition 2014) 74.

Change Suggested by Pre-test Participant	Change made to the Stimulus
Participant 2	
When trying to explain the process, further clarity of the operation of these devices. Communication process: brain, device, prosthetic.	Heading inserted to draw participants to examples of how these devices work.
Have steps setting out how the neural interface device operates – diagram wasn't helpful but confused the participant.	The common steps were added to the stimulus preceding the diagram that symbolically represents the operation of the neural interface device.
More specific examples of how liability might arise would be good. Exactly what types of legal actions that might arise.	Three is enough to stimulate the participant's imagination and a statement was inserted to emphasise this. The examples are not meant to cover the field.
Participant 3	
Neuroprosthetics and interface device and interface system – connection between these.	Sentence removed.
Is it implanted in the brain, is the NID always on, can you turn it off?	The specific technical aspects of the device are not important and stating one type may limit the issues suggested by survey participants. For this reason, no amendment to the stimulus.
Define what civil liability means.	Definition included in the research issue to explain the breadth of the term 'civil liability'.
As at this date, sophisticated explanation of how these devices work.	Heading inserted to draw participants to examples of how these devices work. The common steps were added to the stimulus preceding the diagram that symbolically represents the operation of the neural interface device.
Participant 4	
• Identify any case law if possible.	None available.

Change Suggested by Pre-test Participant	Change made to the Stimulus
Participant 5	
Some of the examples apply to automatic, unintentional reactions, for example, Waving, but some of the other examples weren't quite the same – interaction of artificial and mind while others were exactly what happens in normal life.	Reinforcement added that the examples are limited and the participants are not confined to these types of scenarios.
Provide an understanding of how they connect with the body, how they work etc. Muscle memory. However, the participant understood the operation of the NID as operating like the biological.	Heading inserted to draw participants to examples of how these devices work. Heading and paragraph inserted to clarify the types of neural interface devices that are not included in the research. The common steps were added to the stimulus preceding the diagram that symbolically represents the operation of the neural interface device.
Malfunction was mentioned a number of times.	Heading inserted to make it clear that malfunction is not to be considered.
Use headings: Background, Legal Issues, Scenarios that show how the issues relate to the research issue and Whether civil liability in all aspects or just particular issues.	Headings inserted to better indicate the information contained throughout the stimulus. Reinforcement added that the examples are limited and the participants are not confined to these types of scenarios.

The second five participants in the Pre-test were provided with the updated stimulus that incorporated the changes identified in Table 3.1. The original stimulus with the tracked changes made to the stimulus as a result of the Pre-test is provided in Appendix 3.1. Analysis of responses from the second five participants suggested no substantial changes to the stimulus was required.

C *Conducting the Pilot of the Online Research Instrument*

After the stimulus was finalised,[340] an online research instrument was prepared using Qualtrics Research Suite survey software.[341] The pilot of the online research instrument involved participation of four lawyers to ensure the technical aspects of the instrument were operating correctly. Three of the questions were compulsory:

1. The participants' individual identification code;
2. The professional category in which the participant was working; and
3. Consent to participating in the Delphi Method research.

D *Round 1 of the Delphi Method Research*

Round 1 of the study was conducted to facilitate the identification and description of legal issues based on the research issue defined in the stimulus. Participants were also asked to suggest how the law might address these issues. Initially, eleven Justices of the Supreme Courts throughout Australia agreed to participate while there were nine legal practitioners who were either Partners or Special Counsel of top tier law firms, Queen's Counsel (QC) and Senior Counsel (SC). Seven law academics from universities throughout Australia also agreed to participate.

However, only 12 of these legal experts addressed the Rounds 1 and 2 material.[342] These were three members of the judiciary, four legal practitioners and five law academics. Seven of the participants gave their consent for their professional category to be identified with their comments, so for the purposes of linking those participants to their comments, members of the judiciary are J1 and J2, legal practitioners are L1, L2 and L3 and law academics are A1 and A2. The other participants who did not consent for their professional category to be disclosed are identified as P1 to P7 to enable credit for comments without any attribution to professional category. Anonymity of all the participants has been maintained.

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[340] See Appendix 3.2 The Delphi Method Research Stimulus.

[341] Qualtrics Research Suite survey software was used to capture and analyse responses to the questions in each research instrument. The software enabled different functionality including the ability to construct different question types, embedded data, enable branching, display logic, quotas and email triggers.

[342] Round 1 had eight participants while Round 2 had twelve. Those who had not participated in Round 2 had the opportunity to address exactly the same Round 1 questions and could rank the legal issues in importance.

1 *Round 1 Research Instrument*

The specific type of neural interface device for this research was defined and discussed in the stimulus. The common characteristics of every neural interface device of interest in this research was their ability to:

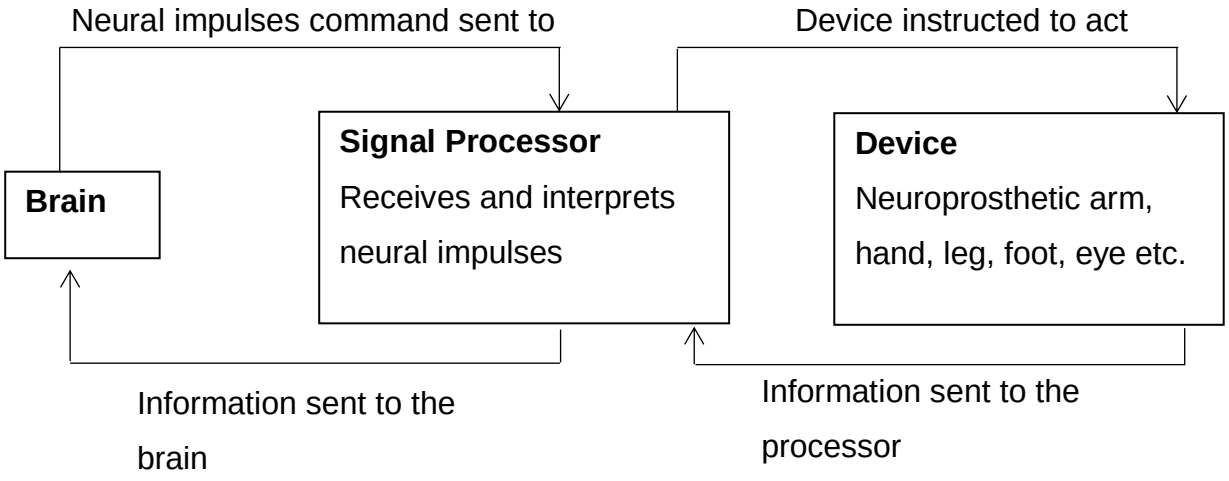
- Sense neural impulses from the brain;
- Interpret the neural impulses through the use of a signal processor;
- Communicate with (that is, send signals to) the brain; and
- Instruct a device to effect a specific action.

The common process that occurs with these types of neural interface devices includes:

- Neural impulse sent from the brain to the signal processor;
- Signal processor interprets the bodily action intended by the neural impulse;
- The signal processor instructs the neuroprosthetic limb or body part;
- The neuroprosthetic limb or body part sends ‘sensory’ information back to the neural processor;
- The neural processor forwards that information on to the brain; and
- The brain receives the information and determines what further commands should be sent to the signal processor and on to the neuroprosthetic limb or body part.

This is can be shown diagrammatically, in Figure 3.2 below.

Figure 3.2 Neural Interface System



The scope of the research issue was clearly stated in the stimulus. Participants were asked to consider the civil liability of the person with, and the manufacturer of, the neural interface device only. They were asked to include all grounds for recovery of loss for property damage and personal injury other than criminal and not to consider any other third party, such as the medical specialists who facilitated the incorporation of the device with the person. It was to be assumed that the neural interface system operated in accordance with the manufacturer's specifications. The facts of every case will be different, so the focus of the study was on the impact of the process of mind, signal processor and device on the law when attributing civil liability for damage to property or person of another.

(a) The Questions

The participants were asked the following questions in Round 1:

1. In what ways do you consider that these neural interface devices may lead to civil liability?
2. What legal issues will arise through the use of such devices?
3. How will the law resolve these issues?
4. What legal principles will be involved?
5. Is there any other information you would like to have in developing your answers to the legal issues?
6. Are there any other legal issues related to the use of these devices which would be of interest?

7. Are there any other comments you would like to make?

Each of the questions provided participants with an opportunity to identify different aspects of the legal framework within which neural interface devices will operate. Questions 1, 2, 4 and 6 were important to enable participants to identify the legal issues that they could anticipate arising with the use of neural interface devices as defined in the stimulus. These legal issues formed the basis for Round 2 where participants were asked to rank the legal issues by allocating them with a value of importance.

2 *Round 1 Research Outcomes*

From the responses by the participants,[343] a summary of the legal issues is as follows:

Legal Issues Identified by Participants Summarised:

1. Negligence including:

    (a) Standard of care.
    (b) Breach of duty of care.
    (c) How courts have treated claims where a contributing factor was the disability of the defendant.
    (d) Reasonable foreseeability/foreseeable risk of harm.
    (e) Reasonable precautions (including insurance cover).
    (f) Reasonableness of defendant's actions.
    (g) Training of the neural interface device user including negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties.
    (h) Neural interface device user acting beyond the limitations of the device – including whether *volenti* arises and user ought not have engaged in the activity.
    (i) Causation.
    (j) Misinterpretation of neural impulses by the device.
    (k) Scope of liability.

[343] See Appendix 3.7.

(l) Strict liability offences e.g. traffic offences.

(m) Manufacturer liability including:

(i) Maintenance required to ensure highest accuracy of the neural interface device;

(ii) Misinterpretation of neural impulses by the device; and

(iii) The device may itself injure the user, giving rise to an action by the user against the manufacturer;

(iv) product liability including consumer protection laws and proportionate liability; and

(v) Manufacturer fear of product liability might be a limiting factor in the development, manufacture and distribution of such devices.

(n) Assuming approval by relevant government bodies, for example the TGA, exposure to liability of government.

(o) Third party claims against neural interface device user and manufacturer.

(p) Defences including ss 5F and 5G *Civil Liability Act*.[344]

(q) Contributory negligence of neural interface device user.

2. Other Legal Issues Summarised:

(a) Legislative reform must be considered very carefully otherwise this will 'freeze' the flexible development of the appropriate law.

(b) Notions of the human body.

(c) Intention.

(d) The appropriateness of surgery etc.

(e) Confidentiality including medical records.

(f) Trespass.

(g) Discrimination.

[344] This was the only time particular provisions of Civil Liability Legislation were identified by participants and both provisions are in the *CLANSW*. Equivalent sections in other Australian legislation are: *CLAQ* ss 13, 14; *Civil Liability Act* 1936 (SA) ss 36, 37; *CLAT* ss 15, 16; *WAVIC* ss 53, 54; *CLAWA* ss 5M, 5N. No equivalent provisions exist in *CLWACT* or *Personal Injuries (Liability and Damages) Act* (NT).

E *Round 2 of the Delphi Method Research*

1 *Round 2 Research Instrument*

The Round 2 research instrument was created to enable each of the legal experts to participate in the Delphi Method research from the stage they had reached in Round 1.

2 *Round 2 Research Outcomes*

Round 2 provided participants with the list of issues that had been identified by all of the participants in Round 1 and all participants were asked to:

- Allocate a level of importance to each of the issues;
- Provide reasons for their ranking;
- Discuss steps the participant believed might be required in order to address each of the legal issues; and
- Provide any further insight or clarification to the responses they had made in Round 1.

When considering the importance of each legal issue that had been identified in Round 1, participants were asked to consider it in the context of the relevant cause of action. If the participant required clarification of a legal issue, a summary of responses from Round 1 was provided in the research instrument. A copy of this summary is available in Appendix 3.6. The value of importance to be allocated to each issue was in accordance with the following scale:

1 = Not at all important;
2 = Slightly important;
3 = Moderately important;
4 = Very important; and
5 = Extremely important.

In Round 2, the way in which participants rated each of the issues is displayed in Table 3.2 below.

Table 3.2 Legal Issues in Order of Allocated Importance

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
1.	Breach of duty of care	0	0	0	4	8	12	4.7
2.	Negligence	0	0	1	2	9	12	4.7
3.	Reasonable foreseeability/foreseeable risk of harm	0	0	0	5	7	12	4.6
4.	Standard of care	0	0	1	3	8	12	4.6
5.	Manufacturer/product liability - consumer laws	0	0	4	1	7	12	4.3
6.	Manufacturer/product liability - proportionate liability	0	0	3	3	6	12	4.3
7.	Reasonableness of defendant's actions	1	0	2	2	7	12	4.2
8.	Defences	1	0	2	3	6	12	4.1
9.	Causation	1	0	2	4	5	12	4.0
10.	Manufacturer/product liability - defences including ss 5F and 5G Civil Liability Act	1	0	4	2	5	12	3.8
11.	Misinterpretation of neural impulses by the device	1	0	3	5	3	12	3.8
12.	Reasonable precautions (including insurance cover)	2	0	2	3	5	12	3.8
13.	Injury to the user, giving rise to an action by the user against the manufacturer	1	0	5	2	4	12	3.7
14.	Training of the neural interface device user	1	1	3	3	4	12	3.7
15.	Neural interface device user acting beyond the limitations of the device	1	2	1	4	4	12	3.7
16.	Third party claims against neural interface device user and manufacturer	1	1	4	3	3	12	3.5
17.	Contributory negligence of neural interface device user	3	0	1	4	4	12	3.5
18.	Scope of liability	2	2	2	1	5	12	3.4
19.	Negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties	1	2	4	2	3	12	3.3

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
20.	Whether *volenti* arises and user ought not have engaged in the activity	2	2	1	4	3	12	3.3
21.	Strict liability offences e.g. traffic offences	2	0	7	2	1	12	3.0
22.	Assuming approval by relevant government bodies, TGA etc., exposure to liability of government	3	1	4	4	0	12	2.8
23.	The appropriateness of surgery etc. to connect neural interface device	4	1	4	3	0	12	2.5

F *Analysis of the Delphi Method Research Outcomes*

Of the twenty-seven legal experts who had agreed to participate in the research, three members of the judiciary, four legal practitioners and five law academics provided responses to the Rounds 1 and 2 questions. A copy of the participant responses is available in Appendix 3.7.

The civil liability issues identified and discussed by participants were predominantly negligence and manufacturer liability. Specific issues that were raised fell under these categories of law and as participant P7 stated:

> In the absence of any special statutory regime, these matters will need to be determined in accordance with the ordinary principles of tort and contract and relevant statutory provisions, for example, the *Civil Liability Act*[345] and the *Australian Consumer Law*.

This was reinforced by comments contributed throughout the research. Legal practitioner L1 identified civil liability as:

[345] Civil Liability Legislation, see above n 72.

> Primarily, claims for breach of duty of care as a consequence of a failure to take reasonable steps to avoid foreseeable risk.

L1 also said:

> Civil claims in connection with breach of duty of care made against both user and manufacturer of device, civil penalties against user of device including in relation to traffic offences.

Member of the judiciary J2 said:

> Where the neural interface device allows the person to perform daily common place activities, such as driving a motor vehicle, but the manner of performing the activity by the person then falls short of the standard of care that applies to any person performing that activity.

Participants were also encouraged to identify the legal principles that the legal profession and judiciary would need to apply in order to resolve the legal issue or civil liability dispute they had predicted. In response to further questions, some participants expanded their view of how further legal issues might flow from the use of the neural interface device as defined in the stimulus.

The ranking of legal issues by importance by each professional category of participant is below in Tables 3.3 through 3.5.

Table 3.3 Ranking of Importance of Issues by Members of the Judiciary

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
1	Negligence	0	0	0	1	2	3	4.7
2	Standard of care	0	0	0	2	1	3	4.3
3	Reasonable foreseeability/foreseeable risk of harm	0	0	0	2	1	3	4.3

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
4	Breach of duty of care	0	0	0	2	1	3	4.3
5	Reasonableness of defendant's actions	0	0	1	1	1	3	4.0
6	Causation	0	0	1	1	1	3	4.0
7	Contributory negligence of neural interface device user	0	0	1	1	1	3	4.0
8	Manufacturer/product liability - proportionate liability	0	0	2	0	1	3	3.7
9	Manufacturer/product liability - consumer laws	0	0	2	0	1	3	3.7
10	Reasonable precautions (including insurance cover)	1	0	0	1	1	3	3.3
11	Defences	0	0	2	1	0	3	3.3
12	Training of the neural interface device user	1	0	0	1	1	3	3.3
13	Injury to the user, giving rise to an action by the user against the manufacturer	0	0	2	1	0	3	3.3
14	Scope of liability	1	0	1	0	1	3	3.0
15	Manufacturer/product liability - defences including ss 5F and 5G Civil Liability Act	1	0	1	0	1	3	3.0
16	Assuming approval by relevant government bodies, TGA etc, exposure to liability of government	1	0	1	1	0	3	2.7
17	Misinterpretation of neural impulses by the device	1	0	1	1	0	3	2.7
18	Neural interface device user acting beyond the limitations of the device	0	2	0	1	0	3	2.7
19	Negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties	1	0	1	1	0	3	2.7
20	Strict liability offences e.g. traffic offences	1	0	2	0	0	3	2.3

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
21	Third party claims against neural interface device user and manufacturer	1	0	2	0	0	3	2.3
22	Whether volenti arises and user ought not have engaged in the activity	1	1	0	1	0	3	2.3
23	The appropriateness of surgery etc to connect neural interface device	2	0	1	0	0	3	1.7

Table 3.4 Ranking of Importance of Issues by Legal Practitioners

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
1	Breach of duty of care	0	0	0	0	4	4	5.0
2	Manufacturer/product liability - proportionate liability	0	0	0	1	3	4	4.8
3	Manufacturer/product liability - consumer laws	0	0	0	1	3	4	4.8
4	Reasonable foreseeability/foreseeable risk of harm	0	0	0	1	3	4	4.8
5	Negligence	0	0	1	0	3	4	4.5
6	Standard of care	0	0	1	0	3	4	4.5
7	Manufacturer/product liability - defences including ss 5F and 5G Civil Liability Act	0	0	1	1	2	4	4.3
8	Third party claims against neural interface device user and manufacturer	0	0	1	1	2	4	4.3
9	Misinterpretation of neural impulses by the device	0	0	1	1	2	4	4.3
10	Reasonableness of defendant's actions	1	0	0	0	3	4	4.0
11	Training of the neural interface device user	0	1	0	1	2	4	4.0
12	Causation	1	0	0	1	2	4	3.8
13	Scope of liability	1	0	0	1	2	4	3.8
14	Defences	1	0	0	1	2	4	3.8
15	Whether volenti arises and user ought not have engaged in the activity	0	1	0	2	1	4	3.8
16	Negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties	0	1	1	0	2	4	3.8
17	Reasonable precautions (including insurance cover)	1	0	1	0	2	4	3.5
18	Neural interface device user acting beyond the limitations of the device	1	0	0	2	1	4	3.5

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
19	Injury to the user, giving rise to an action by the user against the manufacturer	1	0	1	0	2	4	3.5
20	Contributory negligence of neural interface device user	2	0	0	1	1	4	2.8
21	The appropriateness of surgery etc to connect neural interface device	1	0	2	1	0	4	2.8
22	Strict liability offences e.g. traffic offences	1	0	3	0	0	4	2.5
23	Assuming approval by relevant government bodies, TGA etc, exposure to liability of government	1	1	1	1	0	4	2.5

Table 3.5 Ranking of Importance of Issues by Law Academics

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
1	Negligence	0	0	0	1	4	5	4.8
2	Standard of care	0	0	0	1	4	5	4.8
3	Defences	0	0	0	1	4	5	4.8
4	Reasonable foreseeability/foreseeable risk of harm	0	0	0	2	3	5	4.6
5	Contributory negligence of neural interface device user	0	0	0	2	3	5	4.6
6	Breach of duty of care	0	0	0	2	3	5	4.6
7	Reasonableness of defendant's actions	0	0	1	1	3	5	4.4
8	Neural interface device user acting beyond the limitations of the device	0	0	1	1	3	5	4.4
9	Reasonable precautions (including insurance cover)	0	0	1	2	2	5	4.2
10	Causation	0	0	1	2	2	5	4.2
11	Manufacturer/product liability - proportionate liability	0	0	1	2	2	5	4.2
12	Manufacturer/product liability - consumer laws	0	0	2	0	3	5	4.2
13	Manufacturer/product liability - defences including ss 5F and 5G Civil Liability Act	0	0	2	1	2	5	4.0
14	Misinterpretation of neural impulses by the device	0	0	1	3	1	5	4.0
15	Injury to the user, giving rise to an action by the user against the manufacturer	0	0	2	1	2	5	4.0
16	Strict liability offences e.g. traffic offences	0	0	2	2	1	5	3.8
17	Third party claims against neural interface device user and manufacturer	0	1	1	2	1	5	3.6

	Issue	Value Allocated to Issue						
		1	2	3	4	5		
		Not at all important	Slightly Important	Moderately important	Very important	Extremely Important	Total Responses	Mean
18	Whether volenti arises and user ought not have engaged in the activity	1	0	1	1	2	5	3.6
19	Training of the neural interface device user	0	0	3	1	1	5	3.6
20	Negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties	0	0	3	1	1	5	3.6
21	Scope of liability	0	2	1	0	2	5	3.4
22	Assuming approval by relevant government bodies, TGA etc, exposure to liability of government	1	0	2	2	0	5	3.0
23	The appropriateness of surgery etc to connect neural interface device	1	1	1	2	0	5	2.8

The ranking in importance of legal issues provided in Tables 3.3 through 3.5 above, revealed the following with respect to the importance of specific legal issues by the different professional categories of experts:

1. Members of the judiciary and law academics rated negligence and standard of care as the two most important legal issues from the 23 issues identified by participants, that would arise in relation to neural interface devices, while legal practitioners rated breach of duty of care and manufacturer/product liability – proportionate liability as the most important. Legal practitioners rated negligence as the fifth most important and standard of care, sixth.

2. While defences rated highly with law academics at third most important, members of the judiciary rated this 11th most important and legal practitioners rated it 14th.

3. Breach of duty of care rated highest for legal practitioners while members of the judiciary rated it fourth most important and law academics, sixth.

4. Members of the judiciary rated reasonable foreseeability/foreseeable risk of harm in relation to breach of duty of care as third most important legal issue while both legal practitioners and law academics rated it fourth.

5. Reasonableness of the defendant's actions rated fifth most important with members of the judiciary while it rated seventh for law academics and 10th for legal practitioners.

At the other end of the spectrum, there were legal issues that participants generally considered least important in the context of neural interface devices. These included:

1. The appropriateness of surgery to connect neural interface devices was least important for members of the judiciary and law academics with legal practitioners rating it 21st out of 23 in importance.

2. Assuming approval by relevant government bodies, for example, the TGA, exposure to liability of government rated least important for legal practitioners while members of the judiciary rated this higher at 16th out of 23 in importance and law academics 22nd.

3. Strict liability, for example, traffic offences, rated 22nd out of 23 in importance for legal practitioners while it rated 16th out of 23 in importance for law academics and 20th for members of the judiciary.

4. Scope of liability rated 14th out of 23 in importance for members of the judiciary while legal practitioners rated it 13th and law academics rated it 21st.

As discussed in chapter 1[346] and above,[347] this Delphi Method research enables reliance on the wisdom of the experts in determining what are the predominate issues because the predictions by the experts are far more resilient that by a sole researcher. The Delphi Method research conducted did not ask which legal issue would ultimately be examined by the court specifically, but the ranking of importance is a valuable tool to determine this. The Delphi

[346] Under the heading '(b) The Delphi Method Research'.

[347] In chapter 3 under the heading '*1* The Delphi Method'.

Method research was not undertaken, or designed, to assess the reasons for any differences between the professional categories of participants. The research was designed to obtain the collective overall rankings in importance of the legal issues identified by the legal experts. This ranking provided the basis for the subsequent legal analysis undertaken in chapters 4 and 5.

Insight provided by participants in relation to the legal principles and civil liability that might arise with neural interface devices as defined in the stimulus, centred on negligence. The many legal issues identified and ranked high in importance are related to negligence and so the application of the current law of negligence in relation to an incident in which a person with a neural interface device is involved is undertaken in chapter 4. However, without dividing the insight of the experts solely into the elements of negligence, the following discussion gives an overview of participant comments in relation to:

- Civil liability of the manufacturer of the neural interface device.
- Civil liability of the individual with the neural interface device.
- The applicable standard of care to be applied to the individual with the neural interface device when they are a defendant in a negligence action.
- Causation.
- Civil liability of the government or product certification body.

Each of these areas of insight are discussed below. The stimulus specifically excluded malfunction of the neural interface device so product liability and consumer protection legislation were not to be regarded as civil liability issues to be examined.

1 *Civil Liability of the Manufacturer of the Neural Interface Device*

In relation to civil liability of the manufacturer or supplier of the neural interface device, participant J2, a member of the judiciary, expressed the belief that the manufacturer of the neural interface device may be required to indemnify the user of such a device for any damage caused by the negligence of the user, as a result of using the device or to those who suffer property damage or personal injury as a result. Other issues raised by participants in relation to manufacturers included warranties, optimal use, scope of use and operational limits of devices. In relation to device performance representations made by

manufacturers, legal practitioner L2 argued that misleading and deceptive conduct against the manufacturer might arise. With regard to this and the legal issues identified in Round 1, legal practitioner L3 stated:

> One missing is misleading and deceptive conduct (representations that device is more effective/safer than it actually is ... for example). I would say this could be very important. Also, various other aspect of defence/analysis of defect-- adequacy of information provided, failure to warn of risk which materialised.. etc. Again very important.

Various aspects of defence and analysis of any defect will be very important, including the adequacy of information provided and failure to warn of a risk that materialised. Member of the judiciary J2 said, 'Negligence, sale of goods and Australian Consumer Law relating to the supply of goods and/or services' will be of importance. Law academic A1 said the application of key concepts, such as 'acceptable quality' and 'safety defect' under the *CCA* / *ACL*[348] will also be important. Despite the fact that every case will turn on its own facts, participants stated that foreseeability in relation to breach of duty of care will be a significant issue. Factual causation may also be significant. Some defences may be available, such as contributory negligence and the 'obvious risk' defence under Civil Liability Legislation. Analysis of negligence that considers these issues is undertaken in chapter 4.

Despite legal practitioners rating manufacturer liability as second most important, this issue did not constitute substantial discussion. Participants focussed on the liability of the individual with the neural interface device. Member of the judiciary J1 said, 'I agree that negligence on the part of the user will be the most important issue'.

2 *Civil Liability of the Individual with the Neural Interface Device*

Many participants focussed on the actions of the individual with the neural interface device. Where the individual attempts an act that is beyond the limitations of the device, and the individual is aware of this, participants believed that legal issues will centre more on the concepts of reasonable foreseeability of the risk of harm and the objective 'reasonableness' of the individual's actions. An example of liability for any damage caused by the failure to control the neural interface device was provided by participant P1. This liability will arise

[348] *CCA* means *Competition and Consumer Act 2010* (Cth) and *ACL* means *Australian Consumer Law*.

where the user of the device is aware of the limits of their control over the device, or if the individual engaged in activities without giving consideration to any control limitations of the device. Participant P2 considered the situation where the person with the neural interface device is injured by another person and in a negligence action commenced by the device user, the defendant alleges contributory negligence against the user, alleging the limitations of the device meant the user was not taking sufficient care by doing whatever they did.

An analogy provided by P1 is where a person who drives a car, knowing that they have a medical condition that may affect their reflexes from time to time, injures a third party whilst driving.[349] Even though the accident is caused by the manifestation of the condition, they may still be liable in negligence. This scenario resembles *Town of Port Hedland v Hodder (No 2)*:[350]

> I have concluded that the trial judge was wrong to assess contributory negligence without regard to Mr Hodder's disabilities. The proper approach to the question of whether Mr Hodder failed to take reasonable care for his own safety is to ask what conduct might have been expected from a reasonable person in Mr Hodder's situation having regard to his physical disabilities, including most relevantly, his visual impairment.[351]

Participant P7 believes that the conduct a person with a neural interface device might be expected to take would be similar to a person with a physical disability:

> It seems to me that there is a clear analogy with a driver who is blind in one eye or a paraplegic driving a vehicle with modified controls. They will need to adapt their driving practices so as to reduce the risk of causing harm to others. The user of a neural interface device will similarly have to adapt their behaviour so as to avoid causing harm to others.

3 *The Applicable Standard of Care to be Applied to the Individual with the Neural Interface Device when they are a Defendant in a Negligence Action*

The standard of care to be determined in negligence was raised by four of the twelve participants. When identifying the legal issues that will arise, participant P4 suggested:

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[349] *South Australian Ambulance Transport Inc v Walhdeim* (1948) 77 CLR 215.

[350] (2012) 43 WAR 383.

[351] *Town of Port Hedland v Hodder (No 2)* (2012) 43 WAR 383; [2012] WASCA 212, [259] (Martin CJ).

> Standard of care to be determined in negligence. *Volenti* - would it apply if the person with the device undertakes an activity knowing that there may be limitations/delayed reactions?

Law academic A1 said:

> It is likely that the principal challenges in negligence claims against users of NIDs will be in relation to establishing the appropriate standard of care and determining breach… the real challenges will be in establishing the standard of care relevant to the user of the NID. By way of contrast, the principal issues for manufacturers will not involve particularly challenging questions of standard of care.

Member of the judiciary J2 said:

> My thinking at this stage is that the approach to liability will still require some comparison with the usual standard of care expected of any person in the same situation without a neural interface device.

However, Legal practitioner L2 stated:

> The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation.

The training of the recipient of the neural interface device in the use of the device was raised by many of the participants as a factor to be taken into account with regard to breach of the duty of care. The failure to undergo and complete the necessary training in the use of the neural interface device will impact on the liability of the person with the device. Liability could also be attibuted to the trainer as the risk of harm is arguably foreseeable if a person is not properly trained and informed about use of the device. The stimulus limited the scope of liability to exclude a trainer.

Participant P6 regarded the foreseeability of imperfect ‘including imprecise’ responses by the device and training would be crucial:

> The foreseeability of imperfect (including imprecise) responses by the device would seem to be crucial, as would the need for a user to undertake sufficient training in the use of the

> device, lest that shortfall in training be in itself regarded as unreasonable and therefore giving rise to potential liability. Questions will therefore arise as to what level of training should be undertaken by potential users of such devices before they would be considered to have taken reasonable precautions to avoid the consequences of imprecise operation of the device.

Participant P7 believed that a further question will be:

> Whether the user ought not to have engaged in particular activities until such time as they can be completely confident that they are entirely proficient and also fully aware of the limitations of the device.

P7 suggested that the person with the neural interface device should act in accordance with the limitations and capabilities of the device:

> If the user has been appropriately trained and adhered to any limitations upon the use of the device, then they should be in no different position to an able-bodied person who causes injury to another.

It can be concluded that questions will arise as to what level of training should be undertaken by users of such devices before it would be considered that reasonable precautions to avoid the consequences of imprecise operation of the device have been taken.

In summary, when two participants identified standard of care as an issue that would arise, there was no clear identification of whether the fact that the person has a neural interface device should be considered when identifying the applicable standard of care. Two of the participants determined that the standard of care would be that of a person in the same circumstances, without regard to the neural interface device. Three other participants identified the importance of training to ensure the individual understands the ability and limitations of the neural interface device. The issue of standard of care and breach is analysed in chapter 4. In relation to the damage element of negligence, participant P7 believed that resolution of the legal issues in relation to training and appropriate behaviour may give rise to difficult causation questions.

> For example, was the dropping of the antique china plate caused by ordinary negligence or was the cause something unique to the use of this device? If the latter, then matters such as training, adherence to restrictions on use and so forth will arise.

Participant P7 was not the only participant to identify causation as a legal issue that would arise.

4 *Causation*

Six of the twelve participants considered that the issue of causation in the damage element of a negligence action against a person with a neural interface device will be of importance. This issue was centred around the technical aspects of the neural interface device and law academic A1 said ‘Factual challenges will likely arise in causation’ while participant P7 stated, ‘The questions of causation are likely to be difficult’. The technical specifications presented in the stimulus did not include detailed, sophisticated technical specifications but a general operational overview of the device. This was intended to ensure that the discussion by participants could be applied to a range of neural interface devices that function in the way specified. Otherwise, the predicated legal issues and solutions would be confined to only one specific neural interface device whose technical specifications are exactly as defined in the stimulus.

Legal practitioner L2 stated that a technical issue of primary importance will be an evaluation of the risk caused by the imperfect translation of the brain's instructions:

> I analyse it in this way. First, if there were perfect translation of the brain's instructions then one would be analysing the issues of any injury scenario in the usual way: primarily negligence and if there was a prosthetic arm by an examination of whether that made any difference. The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation. And of course, difficulties of proof (because the question of whether, and if so, the degree of imperfect translation will be something entirely within the mind of the defendant).

When considering how the causation difficulties might be resolved, legal practitioner L3 said:

> Given the technology, I would have thought there might be data available to identify causation with some additional precision than contemplated above -- sort of like 'black box data' which could, for example, identify whether the instruction from the brain was turn left but the arm turned right, or not brake (pull instead of push). The availability of something like that would

> be very helpful in the determination of causation. I think people (decision-makers) would be more likely to 'blame' the device maker than the (sympathetic disabled) person using it -- just human nature. Easier to say it malfunctioned and go for deep pocket. Of course, the factual situation may make this easier or harder.

Participant P7 believed that the neural interface device could be considered a ‘mechanical device’, the use of which results in injury to another requiring the court to determine whether this was negligence or a defect in the device. If it is a defect or short coming of the device, participant P7 believed that it will be important to determine whether the defect could have been avoided by the person using the neural interface device or whether liability will fall upon the manufacturer.

Law academic A1 said:

> Also, the act/omission distinction may be challenging … In intentional torts, the concepts of 'intentional' and 'act' will be important.

The issue of causation analysed in chapter 4 provides an opportunity for further consideration as neural interface devices are developed.

5 *Civil Liability of the Government or Product Certification Body*

Participants did not consider that civil liability of the government or a governmental certification body, such as the TGA, was a major legal issue. As outlined in Table 3.2 above, participants rated this as 22nd out of 23 in importance.

G *Resolution of the Civil Liability Issues*

Participants were asked how the current law will resolve legal issues that could arise with the use of neural interface devices as defined in the stimulus. There emerged two distinct arguments provided by participants:

1. The current law as it now exists can be applied to resolve the legal issue; and

2. The current law will need to evolve in order to adequately determine the outcome of the legal issue.

1 *The Current Law*

In relation to the application of the current law, some participants believed that civil claims will be determined in accordance with established principles. Some participants believed issues of new technology will be subsumed under existing legal categories, such as torts law.

Member of the judiciary J2 said:

> The law will resolve these issues by applying the tort principles and those statutory provisions that cover supply of goods and services.

Another member of the judiciary J1 said:

> I agree that they will be dealt with through orthodox legal principle and applicable statute law.

Legal practitioner L1 said:

> I expect that courts will determine civil claims … in accordance with established principles and will not seek to devise solutions or exemptions to 'excuse' or mitigate the liability of users and manufacturers. Any solution in the manner of exemptions etc will need to be driven by legislative reform.

Law academic A2 said:

> Negligence and its components provides a networked approach to deciphering the legal issues.

Participant P7 said:

> I cannot see any basis to take a special approach to the resolution of these issues … The user of a neural interface device will similarly have to adapt their behaviour so as to avoid causing harm to others.

Member of the judiciary J2 said:

> These questions require some imagination in making the responses. My thinking at this stage is that the approach to liability will still require some comparison with the usual standard of care expected of any person in the same situation without a neural interface device.

Other participants were unsure whether the use of such devices will take the law into unchartered territory or require the development of new principles:

> I do think that the High Court, if it was required to look at this issue, would apply established principles to the circumstances of individual cases. Any comprehensive consideration of the legal issues which arise would seem to involve an amalgam of laws related, for example, to motor vehicle manufacturers and to those governing the introduction of new drugs. I don't think these legal issues are truly novel, rather they require the application of streams of law which seem to me to be fairly well developed.

Law academic A1 said:

> Negligence and its components provide a networked approach to deciphering the legal issues … Arguably, there could be a statutory response (though it is difficult to see why this would be justified as the general principles are likely to be adequate to deal with civil liability in this context).

Law academic A2 said:

> It does not seem to me that there is anything particularly special about this context for the application of duty of care and causation principles, though there will clearly be factual challenges in the latter.

Legal practitioner L3 captured the perspective of the participants who believed the current law will adequately resolve civil liability disputes involving neural interface devices:

> It seems to me that the issues give rise to no new issue of legal principle: It's just the application of the facts within existing principle. The issues which I have identified as not important are mostly subsumed within the issues I have identified as extremely important.

> On the scenario in which the only flaw in the use of the device is the risk of imperfect translation of the brain's instructions, then the questions of what standard of care the law of negligence imposes will be obvious. The real issue will be breach, causation, foreseeability all of which will involve understanding the extent of the risk of imperfect translation and what should have been the reaction of the user and the person who enabled the user to use the device. The law's response to that will be evaluated through the aspects of the laws of negligence which I have highlighted and also through the analogous consumer protection provisions in the *ACL* and any statutory specific regulation.

However, other participants who recognised the pressure on the current law that will be exerted by these innovative neural interface devices that are incorporated into the human body, said the current law will need to change.

2 *Development of Current Law*

Participants who raised the need for development of the current law to adequately resolve civil liability disputes involving neural interface devices, are relying on the common law legal system, together with both consumer protection legislation and Civil Liability Legislation, being able to adapt. Participant P6 stated:

> Our common law tradition, particularly in relation to negligence issues, would indicate that a body of relevant law will develop incrementally as the courts consider individual cases as they arise.

Law academic A1 identified such development as a 'principled and incremental development of existing principles of the law of negligence and statutory interpretation' while law academic A2 said the development of the common law would occur 'probably by a step by step and evolving approach'. This will include determination of 'control' a person will have over the neural interface device. Analogies will be applied such as parties who have a physical disability or 'the operation of cars and other equipment.'[352]

Training of the person to operate the neural interface device and to understand the limitations of the device in order to engage with the surrounding community were factors identified by participants that will be considered by the court when determining breach of

[352] Law academic A2.

standard of care. However, participant P6 said that issues of training and reasonable precautions:

> might well be tempered by 'social utility' arguments, which would propose that the benefit received by the use of the device warrants a level of risk taking that might otherwise be considered unreasonable.

In relation to the development of the law, legislative intervention was discouraged by many participants. Participant P6 stated:

> I would suggest that the complexities of these questions are such that they would be best left to the common law to resolve, and that interested parties should be very cautious about seeking legislation, as this will “freeze” the flexible development of appropriate laws.

Development of the law in this area will also have insurance and policy considerations. Participant P6 commented:

> The insurance issues mentioned above will probably be crucial to these decisions, as the courts seek to balance the social utility of such devices against the protection of third parties from potential 'malfunctions'. Courts will ask 'who should pay?' for any damage which arises and this will be a difficult decision.

Participant P5 said:

> It may be worthwhile to think of alternatives to the courts to resolve disputes in this area - such as a comprehensive insurance or disability scheme - or the use of a 'manufacturers ombudsman' - an avenue where resolution does not rely on a legal cause of action and the associated cost and expense.

Participant P6 said:

> It would seem to me that any user of such a device would be well advised to take out insurance to cover the possibility of imperfect performance of the device, as such a precaution might well be considered to be the appropriate (and therefore 'reasonable') response to such potential incidents.

3 *Identification of Further Information Required*

Participants were also asked what further information, beyond that provided in the stimulus, they felt would assist in resolution of the civil liability issues identified. This was particularly important because a civil action against a defendant with a neural interface device as defined in the stimulus has yet to come before the court. In anticipation of such a case, information identified by the participants will be important in resolving the dispute. The additional information sought by participants centred on the neural interface device itself. The nature, predictability and frequency of inability of the neural interface device to accurately interpret the neural impulse, and the general reliability of individual devices, would be central to any such considerations. For example, member of the judiciary J2 identified questions that may play a role in determining liability:

> Is there previous experience of death or serious injury or significant property damage caused by the lack of accuracy or the signal processor being unable to interpret neural impulses with 100% accuracy? Are there conditions (e.g. extreme temperatures) in which the signal processor will be unlikely to interpret the neural impulses with accuracy and which therefore should be avoided by the user of the neural interface device?

Legal practitioner L2 said:

> If the extent of risk of imperfect translation is the real issue, then information concerning the way in which the translation works scientifically; then information about evaluating the size of the risk; how that was communicated to the user; and evidence concerning the particular mechanics of what happened on the day of the incident: to what extent if at all did imperfect translation actually occur and if it did to what extent was it causative.

Further, legal practitioner L1 said:

> Ultimately, answers to these questions will turn on the extent to which there are factors which 'excuse' or act in mitigation so as to minimise exposure of users and manufacturers to accepted civil and criminal law standards. It may be important to understand the extent to which each category of persons understands the limitations on their ability to control the devices and how to manage risk through avoidance of risky activities etc. also any other ways in which risks can be identified and mitigated.

This additional information identified by participants will most likely be available when a matter comes before the court and will play a role in the resolution of a civil dispute involving a person with a neural interfaced device.

Consideration by the participants of the development of the current law, therefore, provided support for adaptation of the common law and application of Civil Liability Legislation that will enable civil disputes to be resolved.

H *Summary*

Having identified legal issues that will arise as a result of the defendant having a neural interface device, participants appeared confident the common law would be a more appropriate vehicle for resolving the issues rather than the introduction of legislation that could stifle the development of neural interface devices or freeze the development of appropriate common law in this innovative field. The Delphi Method research undertaken to determine the legal issues that might arise with respect to civil liability and neural interface devices, as defined in the stimulus, identified negligence to be the dominant cause of action. Where a person with a neural interface device is a defendant in a cause of action in negligence, related factors such as causation and reasonableness of the defendant's actions including training and precautions undertaken, were also identified by the experts as important. Product liability pursuant to consumer protection legislation and proportionate liability were also regarded as important issues that were likely to arise in relation to safety defects. However, as the stimulus excluded malfunction of the neural interface device, product liability, consumer protection legislation and proportionate liability are not examined.

Through the use of the Delphi Method, the outcomes have captured insightful contributions from legal experts to more accurately predict the legal issues that will arise with the merging of mind and machine. The purpose of having identified these legal issues was to ground the importance of analysis of the issues throughout this thesis and that will assist the judiciary, legal profession and legislature in preparing for a corresponding civil dispute. Chapter 4 analyses the issues raised by the participants in relation to negligence while chapter 5 analyses liability of the manufacturer. As more sophisticated neural interface devices operate in the way defined in the stimulus, become available and are integrated into human beings, the legal issues predicted by the legal experts in this research will be determined by the courts. With innovation comes new challenges and it appears from this research that

neural interface devices will be no exception. The subsequent analysis in chapters 4 and 5 provided support for the recommendations in chapter 6.

The Delphi Method research enabled investigation of the research hypothesis that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action. Progress towards the determination of this hypothesis using the concept of revolutionary science developed by Thomas Samuel Kuhn,[353] as discussed in chapter 1, was achieved. The Delphi Method research identified tension between legal experts regarding the participants' belief in the ability for the current common law and legislation to resolve the legal issues identified. This could give rise to anomalous results in relation to the application of the current law in determining a civil dispute, most prominently in a negligence action. Approximately half of the legal experts in the Delphi Method research identified a need for the current law to adapt.

Chapter 4 analyses the negligence issues raised by the legal experts in determining the standard of care that will be applied to a person with a neural interface device and the challenges with causation when harm occurs to the property or person of another. Adaptation of the current law, both common law and legislation, could enable the courts to better resolve civil liability proceedings that involve a party with a neural interface device.

[353] Kuhn, above n 2.

IV CHAPTER 4 NEGLIGENCE

A *Introduction*

Chapter 3 provided the outcomes of the Delphi Method research. Legal experts, including Judges of Supreme Courts, Queens Counsels, Partners and Special Council of top tier law firms and university law academics throughout Australia, identified the legal issues that would arise with respect to civil liability and neural interface devices. These legal experts identified negligence as the most important legal issue so this chapter provides analysis of the elements of negligence in the context of the research hypothesis.

Negligence proceedings in Australia are determined within a fault-based, common law system. To succeed in a negligence action, the plaintiff needs to establish, on the balance of probabilities, that: The plaintiff was owed a duty of care by the defendant, the defendant breached that duty of care, and that the breach of the duty of care was both the factual cause of the damage sustained by the plaintiff and that the damage is within the scope of the defendant's liability.

The range of circumstances in which a duty of care is owed by one to another (fellow road users, employer and employee and the like) is very well traversed. Whether a person has a neural interface device or not is unlikely to affect whether that person owes a duty to another in respect of existing, recognised categories. Proving a breach of duty and factual causation will be considerably more difficult where there has been melding of mind and machine. For the purposes of this analysis, it will be assumed that the defendant, who has a neural interface device, owes a duty of care to the plaintiff.

As Delphi Method research participant law academic A2 said:

> It does not seem to me that there is anything particularly special about this context for the application of duty of care and causation principles, though there will clearly be factual challenges in the latter.

While most of the Civil Liability Legislation recognises what duty of care or negligence means,[354] the negligence cause of action is at common law so the duty of care is also at common law. However, modification of the common law has occurred through the introduction of Civil Liability Legislation.

B *Statutory Modification of the Common Law*

In 2002, the Australian Government commissioned an examination of 'a method for the reform of the common law with the objective of limiting liability and quantum of damages arising from personal injury and death.'[355] Amongst a number of requests in the Terms of Reference announced on 2 July 2002, the panel of experts chaired by the Honourable David Andrew Ipp were to:

> 1 Inquire into the application, effectiveness and operation of common law principles applied in negligence to limit liability arising from personal injury or death, including:
>
> (a) the formulation of duties and standards of care;
>
> (b) causation;
>
> (c) the foreseeability of harm;
>
> (d) the remoteness of risk;
>
> (e) contributory negligence; and
>
> (f) allowing individuals to assume risk.[356]

The common law principles as applied in negligence were investigated and Recommendation 1, in the final report titled *Review of the Law of Negligence – Final Report* ('Ipp Report'), was that each jurisdiction should introduce civil liability legislation to incorporate all of the recommendations of the Panel.[357] The overarching Recommendation 2 was that:

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[354] ***Duty of care*** means a duty to take reasonable care or to exercise reasonable skill (or both duties): *CLAQ* Schedule 2; ***Duty*** means – (a) a duty of care in tort; or (b) a duty of care under contract that is co-extensive with a duty of care in tort; or (c) another duty under statute or otherwise that is co-extensive with a duty of care referred to in paragraph (a) or (b); *CLAT* s 3; **"*negligence*"** means failure to exercise reasonable care and skill: *CLANSW* s 5; ***Duty of care*** means a duty to take reasonable care or to exercise reasonable skill (or both): *CLAS* s 3; ***Negligence*** means failure to exercise reasonable care: *WAVIC* s 43; "***negligence***" means failure to exercise reasonable care and skill': *CLWACT* s 40. There is no equivalent provision in the Northern Territory or Western Australia.

[355] Commonwealth of Australia, *Review of the Law of Negligence – Final Report*, (2002), ix ('Ipp Report').

[356] Ipp Report, ix.

[357] Ibid 35.

> The Proposed Act should be expressed to apply (in the absence of express provision to the contrary) to any claim for damages for personal injury or death resulting from negligence regardless of whether the claim is brought in tort, contract, under a statute or any other cause of action.[358]

As a result, the introduction of Civil Liability Legislation in the Australian Capital Territory and States throughout Australia was a modification of the common law. To the extent that the Ipp Report recommendations conflicted with common law principles, the legislation overrides the common law. As reinforced by Recommendation 2, the legislation applies in a common law negligence action. The Civil Liability Legislation does not create a cause of action so the duty of care owed by the defendant in a negligence action is at common law. The Civil Liability Legislation modified the common law by providing a framework to determine breach of the common law duty of care and in doing so, the legislation substantially reflected the common law.[359] In a negligence action, a person cannot be held liable for failure to take precautions against a risk that could be described as 'farfetched or fanciful',[360] however, the legislation changed the common law term of 'farfetched or fanciful' to 'not insignificant'.[361]

> The phrase "not insignificant" is intended to indicate a risk that is of a higher probability than is indicated by the phrase "not far-fetched or fanciful", but not so high as might be indicated by a phrase such as "a substantial risk". The choice of a double negative is deliberate. We do not intend the phrase to be a synonym for "significant". "Significant" is apt to indicate a higher degree of probability than we intend.[362]

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[358] Ibid 36.

[359] For example, 'The determination of factual causation under s 5D(1)(a) is a statutory statement of the "but for" test of causation (30): the plaintiff would not have suffered the particular harm but for the defendant's negligence.': *Strong v Woolworths* (2012) 246 CLR 182, 190 [18] (French CJ, Gummow, Crennan and Bell JJ); 'Causation is an element in the tort of negligence on which the plaintiff bears the burden of proof. This was so at common law and remains the case under s 5E of the Civil Liability Act 2002 (NSW) (the Act)': *Strong v Woolworths* (2012) 246 CLR 182, 199 [43] (Heydon J); 'The references to "balance of probability" reveal that Megaw LJ is imposing a legal (ie persuasive) burden on the defendant (94). That is not the rule in Australia at common law (95). Nor is it the rule under s 5E': *Strong v Woolworths* (2012) 246 CLR 182, 206 [59] (Heydon J).

[360] *Wyong Shire Council v Shirt* (1980) 146 CLR 40.

[361] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B.

[362] Ipp Report, 105 [7.15].

When applying the Civil Liability Legislation to determine breach of duty of care, the court will look to the common law through the lens of the legislation.[363] That is, the Civil Liability Legislation is the statutory modification of the common law and the court now applies that legislation to determine breach of the duty of care.[364] Arvind and Steele capture this when they stated, 'Indeed, what we call "common law" itself is the product of both statutory and judicial action'[365] and Stewart and Stuhmcke, 'the common law of negligence provides the context for statutory interpretation in informing the *development* and *application* of the tort of negligence'.[366] In this way, the standard of care and breach of that standard is determined through the application of the legislation. In establishing whether a person has breached the duty of care in terms of a failure to take precautions against the risk of harm, the risk must be foreseeable, that is, a risk an ordinary person foresaw, or ought to have foreseen. That risk must have been not insignificant and in the circumstances, a reasonable person in the position of the defendant would have taken the precautions.

C *Breach of Duty of Care*

1 *Standard of Care*

Should the standard of care for a person with a neural interface device be different from the standard of care that normally applies? The person with a neural interface device has the potential to have a different objective standard of care determined through the application of the Civil Liability Legislation because the qualitative difference between the device and a biological limb or body part is such that the device cannot be considered as having the degree of complexity and sophistication as its biological counterpart. . Members of the judiciary and law academics who participated in the Delphi Method research rated negligence and standard of care as the two most important legal issues, that would arise in

[363] For example, 'The determination of factual causation under s 5D(1)(a) is a statutory statement of the "but for" test of causation (30): the plaintiff would not have suffered the particular harm but for the defendant's negligence.': *Strong v Woolworths* (2012) 246 CLR 182, 190 [18] (French CJ, Gummow, Crennan and Bell JJ). '…breach of duty and causation and damages are often decisively influenced by statute': Mark Leeming, 'Theories and Principles Underlying the Development of the Common Law – The Statutory Elephant in the Room' (2013) 36(3) *UNSW Law Journal* 1002, 1006.

[364] Ibid.

[365] TT Arvind and Jenny Steele, 'Bringing Statute (Back) onto the Radar: Implications' in TT Arvind and Jenny Steele (eds), *Tort Law and the Legislature: Common Law, Statue and the Dynamics of Legal Change* (Hart, 2013) 451, 451.

[366] Pam Stewart and Anita Stuhmcke, 'The rise of common law in statutory interpretation of tort law reform legislation: Oil and water or a milky pond?' (2013) 21 *Torts Law Journal* 126, 128 (emphasis supplied).

relation to neural interface devices. Whether or not a different objective standard of care will apply to a person with a neural interface device is unclear.

In *Imbree*, Justice Kirby outlined the common law approach to determination of the standard of care:

> The common law recognises many circumstances in which the standard of care expected of a person takes account of some matter that warrants identifying a class of persons or activities as required to exercise a standard of care different from, or more particular than, that of some wholly general and "objective community ideal" (125). Chief among those circumstances is the profession of particular skill. A higher standard of care is applied in those cases. That standard may be described by reference to those who pursue a certain kind of occupation, like that of medical practitioner, or it may be stated, as a higher level of skill, by reference to a more specific class of occupation such as that of the specialist medical practitioner (126). At the other end of the spectrum, the standard of care expected of children is attenuated (127).
>
> The essential question: The fundamental question for decision is whether, as this Court held in *Cook*, the content and ambit of any duty of care owed to a person in the position of the appellant is what is "reasonably to be expected of an unqualified and inexperienced driver in the circumstances"? Alternatively, is it a single, universal, objective standard of care applicable to all drivers (experienced and inexperienced; skilled and unskilled; licensed and unlicensed) when they undertake the driving of a motor vehicle on a public road?[367]

The court now applies the Civil Liability Legislation but will look to the objective test under the common law when determining the standard of care in a matter.[368] The court must establish what a person would have done in the particular situation by considering all the materially relevant facts of the matter at hand.[369] Courts have generally been reluctant to consider the peculiar characteristics of the person in order to move away from the reasonable person, the objective standard of care.[370] Moran states the theoretical reason

[367] *Imbree v McNeilly* (2008) 236 CLR 510, 532-33 [69], 548 [125] (footnotes omitted).

[368] See *Glasgow Corporation v Muir* [1943] AC 448, 454; *Bolton v Stone* [1951] AC 850, 860; *Paris v Stepney Borough Council* [1951] AC 367, 384. See also *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B.

[369] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B. See also Amanda Stickley, *Australian Torts Law* (LexisNexis Butterworths, 4th ed, 2016) 245-6 [11.3]-[11.7].

[370] *Carrier v Bonham* [2002] 1 Qd R 474. See also Carolyn Sappideen and Prue Vines P (eds) *Fleming's the Law of Torts* (10th ed, Thomson Reuters, 2011) [7.20].

for this is that 'the objective standard "eliminates the personal equation and is independent of the idiosyncrasies of the particular person whose conduct is in question".'[371]

> As the common law's tool for identifying behaviour that attracts neither censure nor legal liability, the reasonable person plays a central role in the law of negligence. The actions of the litigant (plaintiff or defendant) are compared to what the reasonable person would have done in like circumstances. Only those who emulate the reasonable person will be considered 'faultless' and hence believed of the consequences of their actions. In this sense then the behaviour of the reasonable person defines the content of the renowned objective standard of the law of negligence: a standard that, thou it does not demand perfection, does insist upon a certain level of prudence or attentiveness to the interests of others. Thus, the fault element or standard of care in negligence: the objective standard.[372]

The neural interface device cannot be considered identical to a biological limb. The ability of the device to interpret neural impulses, whilst very good, is not functionally equivalent.[373] The general common law rule which applies in determining cases where the plaintiff is seeking damages for negligence, weighs against the court taking into account the specific characteristics of the defendant.[374] However, through the application of the Civil Liability Legislation, differences between a defendant with a neural interface device and a defendant without such a device could be recognised. In relation to the common law, McTiernan ACJ in *McHale v Watson* considered whether special circumstances could be taken into account when determining the standard of care:

> It seems to me that the present case comes down to a fine point, namely whether it was right for the trial judge to take into account Barry's age in considering whether he did foresee or ought to have foreseen that the so-called dart might not stick in the post but be deflected from it towards Susan who was in the area of danger in the event of such an occurrence. I think that there is no ground for disagreeing with the conclusion of Windeyer J. on this question.[375]

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[371] Mayo Moran, *Rethinking the Reasonable Person: An Egalitarian Reconstruction of the Objective Standard* (Oxford University Press, 2003) 20-21. Attribution for the quote is provided by Moran as *Glasgow Corp v Muir* [1943] AC 448, 457 (Lord MacMillan).

[372] Ibid 18.

[373] Kengo Ohnishi, Richard F Weir and Todd A Kuiken, 'Neural machine interfaces for controlling multifunctional powered upper-limb prostheses' (2007) 4(1) *Expert Review of Medical Devices* 43, 43. See also discussion under the heading '*D* Limitations of Neural Interface Device Technology'.

[374] *Nettleship v Weston* [1971] 2 QB 691, 707-709 (Megaw LJ); *McHale v Watson* (1966) 115 CLR 199, 228 (Owen J) citing Lord Macmillan in *Glasgow Corporation v Muir* [1943] AC 448; *Imbree v McNeilly* (2008) 236 CLR 510, 544 [112] (Kirby J).

[375] (1966) 115 CLR 199, 210.

Windeyer J had concluded that such a particular characteristic of the defendant should be considered. Kitto J stated:

> I take this to mean that the test to be applied in determining whether the appellant's injury resulted from a breach of a duty owed to her by the respondent should be stated not in terms of the reasonable foresight and prudence of an ordinary person, but in terms of the reasonable foresight and prudence of an ordinary boy of twelve; and that the respondent should succeed because an ordinary boy of twelve would not have appreciated that any risk to the appellant was involved in what he did.[376]

Kitto J discussed the development of common law principles in actionable negligence[377] and contributory negligence[378] and in concluding that the trial judge had made no error of law, his Honour said:

> Sympathy with the injured girl is inevitable. One might almost wish that mediaeval thinking had led to a modern rule of absolute liability for harm caused. But it has not; and, in the absence of relevant statutory provision, children, like everyone else, must accept as they go about in society the risks from which ordinary care on the part of others will not suffice to save them. One such risk is that boys of twelve may behave as boys of twelve; and that, sometimes, is a risk indeed.[379]

Owen J also considered the common law development of an objective standard,[380] concluding that Windeyer J was correct and stated:

> For these reasons I am of opinion that Windeyer J. rightly took into consideration the fact that Barry Watson was only twelve years old and that he did not misdirect himself as to the degree of care reasonably to be expected of a boy of that age.[381]

Circumstances like this where the courts have decided to vary the objective standard provide support for a different standard of care for those with neural interface devices. These include

[376] *McHale v Watson* (1966) 115 CLR 199, 211.
[377] Ibid 212-14.
[378] Ibid 214-15.
[379] Ibid 216.
[380] Ibid 228-234.
[381] Ibid 234.

not only age[382] but also skill or knowledge.[383] That is not to say that these different standards of care allow a special rule for other groups, but to show that in particular circumstances the court will apply a different standard of care from that applied to others without the specific characteristics of the person in question. Dietrich and Field considered when, as a matter of law, the courts ought to take into account a person's characteristics before the standard ceases to be objective.[384] In their opinion:

> [P]rovided that (1) the person whose conduct is in question possesses the capacity to act reasonably, and (2) the question of whether that person's conduct was in fact reasonable can be answered by reference to some measurable criteria to which the reasonable person can relate (such as mental age or physical mobility), then the test is still at its core an objective one.[385]

In comparison, the United States *Restatement (Third) of Torts:* Physical & Emotional Harm §3 (2010) (Negligence), incorporating the Restatement Second of Torts §283 (Conduct of a Reasonable Man: The Standard), affirms that the balancing approach to the standard of care has been applied in a large majority of the courts throughout the United States.[386] The *Restatement (Third) of Torts* also provides support for the court's recognition of a different standard of care for specific classes of defendant.[387] These different standards of care highlight the court's willingness to consider the special circumstances that exist with a specific class of individuals.

The standard of care could be an extension or variation of an existing standard of care, such as the objective standard in respect of the particular class of people with a neural interface device. Such a variation or extension might go so far as establishing a new or novel standard of care to the extent that the standard becomes that of a reasonable person with the same,

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[382] See *McHale v Watson* (1966) 115 CLR 199.

[383] See *Rogers v Whitaker* (1992) 175 CLR 479.

[384] Joachim Dietrich and Iain Field, 'The "Reasonable Tort Victim": Contributory Negligence, Standard of Care and the "Equivalence Theory" (2017) 41 *Melbourne University Law Review* 602, 629-32.

[385] Ibid 629 (footnotes omitted).

[386] American Law Institute, *Restatement (Third) of Torts, Liability for Physical and Emotional Harm* (American Law Institute, 2012). Expressed by Judge Learned Hand in *United States v Carroll Towing Co* 159 F.2d 169 (1947).

[387] American Law Institute, above n 386. In comment *d. Reasonable care and the primary factors* to §3, the following is stated: 'These categories include cases involving emergencies (§9), cases involving actors who are children (§10), and cases involving actors with disabilities (§11). Section 12, addressing the specific knowledge and skills of the actor, and §13, concerning the role of custom also supplement the primary factors contained in this Section,' that is §3.

or similar, neural interface device in the same, or similar, circumstances. If such an extension or variation does not occur, the fact that the person has a neural interface device could be considered when determining breach of the duty of care.[388]

In determining a breach of this standard, a court will consider whether, as a result of extensive training in the operation of the device by a neural interface device technician, the person will know of the potential risks of the neural interface device not functioning in complete compliance with the neural impulses as intended. The risk may well be regarded as reasonably foreseeable and if determined to be not insignificant, then the person will be expected to take reasonable precautions.[389] Members of the judiciary who participated in the Delphi Method research rated reasonable foreseeability/foreseeable risk of harm in relation to breach of duty of care as third most important legal issue while both legal practitioners and law academics rated it fourth.

In determining whether a defendant with a neural interface device might be considered as a different class from those who do not have a neural interface device, the class of people with skill or knowledge needs to be considered.

2 *Training and Expertise*

The functional difference between a biological limb and the neuroprosthetic limb may require a person who has a neural interface device integrated into his or her body to undertake a degree of training before using the device. This training by medical physicians, occupational therapists, physiotherapists, psychologists and neural interface device technicians would lead to the development of knowledge regarding the limitations and possible adverse responses the neural interface device may have.[390] The liability of third parties, such as these trainers, is excluded from analysis undertaken.[391] While legal experts in the Delphi Method research identified negligence of the trainer, that is, nature and extent of trainer's duty of care to third parties, as a possible legal issue that could arise, it was rated 19th out of 23 in importance. The primary focus of the legal issues identified by the legal experts was on the liability of the person with the neural interface device and the training of this person was rated 14th out of 23 in importance.

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[388] *CLANSW* s 5B; *CLAQ* s 9, *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B. See also Stickley, above n 369, 261 [11.46].

[389] Ibid.

[390] The Delphi Method research stimulus limited consideration of liability to that of the person with the neural interface device and the manufacturer of the device, so analysis of liability for others is not provided.

[391] See discussion in chapter 1 under the heading 'Other Considerations Outside the Scope of this Thesis'.

The training might enable a person to achieve a level of expertise to such a degree that the standard of care determined by the court may be greater than a person without a neural interface device. The skill in operating the device could be regarded as a specialised skill. While the training and expertise would be far less than that required to perform specialised medical procedures, or tasks involving specialist training such as those undertaken by qualified electricians, the training undertaken by the person with a neural interface device would provide them with skills that a person without a neural interface device would not have. This might also occur where the neural interface device is such that it enhances human attributes, that is, provides individuals with abilities beyond those of the biological limb or body part. Delphi Method research participant P7 suggested that the person with the neural interface device should act in accordance with the limitations and capabilities of the device:

> If the user has been appropriately trained and adhered to any limitations upon the use of the device, then they should be in no different position to an able-bodied person who causes injury to another.

An example of the way in which the standard of care has differed as a result of skill or knowledge, is with respect to medical practitioners. In *Rogers v Whitaker*, for example, the High Court held:

> The standard of reasonable care and skill required is that of the ordinary skilled person exercising and professing to have the special skill, in this case the skill of an ophthalmic surgeon specialising in corneal and anterior segment surgery.[392]

This would include the provision of information by the medical practitioner to assist the patient in providing informed consent to the medical procedure.[393] The obligation to provide information is now required under some of the Civil Liability Legislation.[394] Likewise, many professions attract a different standard of care including lawyers, engineers, valuers,

[392] *Rogers v Whitaker* (1992) 175 CLR 479, 483. See *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 586. See also *Whitehouse v Jordan* [1981] 1 WLR 246, 258 (Lord Edmund-Davies); *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634, 638 (Lord Scarman). See also Civil Liability Legislation, for example, *CLANSW* s 5O, *CLAQ* s 22, *CLAS* s 41 *CLAT* s 22, *WAVIC* s 48.

[393] In *Rogers v Whitaker* (1992) 175 CLR 479, 490, the High Court held that 'The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment.'

[394] *CLAQ* s 21; *CLAT* s 21 and *WAVIC* s 50.

accountants, manufacturers, and builders.[395] Generally, the standard is that of an ordinary skilled member of that profession who acts with reasonable care and skill. However, the relevant standard applied to a particular profession was not conclusive at common law,[396] but now Civil Liability Legislation provides a mechanism to determine whether or not a breach of the duty of care has occurred.[397] That standard of care is applied to the facts of a case to enable the court to ascertain whether or not there has been a breach of the duty of care owed by the professional. Application of this principle to the determination of the appropriate standard of care to be applied to a defendant with a neural interface device is discussed further below under heading '*3* Application of the Factors Determining Standard of Care. The analysis concludes that extensive training in the operation of the device will not result in a higher standard of care but will impact on determining breach of the duty of care.

3 *Application of the Factors Determining Standard of Care*

When looking at the common law through the lens of the Civil Liability Legislation there are circumstances in which the standard of care expected of a person takes account of some matter or activities that require a standard of care different from, or more particular than, that of some wholly general and objective community ideal.[398] For example, as noted above, a different standard of care has been recognised by the courts for various classes of defendants including children, professionals, and persons with a physical disability.[399] However, the onus of establishing facts giving rise to such a special or different class or category will be upon the party asserting it.[400]

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[395] See for example, *Heydon v NRMA Ltd* (2000) 51 NSWLR 1; [2000] NSWCA 374 (lawyers); *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* (2004) 216 CLR 515 (engineers); *Smith v Eric S Bush* [1990] 1 AC 831 (valuers); *Hardie (Qld) Employees Credit Union Ltd v Hall Chadwick & Co* [1980] Qd R 362 (accountants); *Donoghue v Stevenson* [1932] AC 562; *Grant v Australian Knitting Mills Ltd* [1936] AC 85; *Suosaari v Steinhardt* [1989] 2 Qd R 477 (manufacturers); *Bryan v Maloney* (1995) 182 CLR 609 (builders).

[396] *Florida Hotels Pty Ltd v Mayo* (1965) 113 CLR 588, 593 and 601; *Naxakis v Western General Hospital* (1999) 197 CLR 269; *Rogers v Whitaker* (1992) 175 CLR 479.

[397] *Rogers v Whitaker* (1992) 175 CLR 479, 483. See also Civil Liability Legislation throughout Australia, for example, *CLANSW* s 5O; *CLAQ* s 22; *CLAS* s 40; *CLAT* s 22; *WAVIC* s 48.

[398] *Imbree v McNeilly* (2008) 236 CLR 510, 527 [69].

[399] See, for example, *McHale v Watson* (1966) 115 CLR 199 (children); *Rogers v Whitaker* (1992) 175 CLR 479 (medical practitioners); *Heydon v NRMA Ltd* (2000) 51 NSWLR 1 and *Badenach v Calvert* (2016) 257 CLR 440, *D'Orta-Ekenaike v Victoria Legal Aid* (2005) 223 CLR 1 and *Butcher v Lachlan Elder Realty Pty Ltd* (2004) 218 CLR 592; (lawyers); *South Australian Ambulance Transport Inc. v Walhdeim* (1948) 77 CLR 215; *CLAS* s 31(2) (physical disability).

[400] *Imbree v McNeilly* (2008) 236 CLR 510, 527 [48] (Gummow, Hayne and Kiefel JJ) citing *Cook v Cook* (1986) 162 CLR 376, 387.

These different standards of care are based on one or more factors, many of which were discussed by the High Court in *Imbree*[401] which involved a review of the standard of care to be applied to an inexperienced car driver. In this case, the first respondent, Jessie McNeilly, was a young man of 16 years of age who did not have a learner's permit and this was known by the appellant, Paul Imbree, who allowed McNeilly to drive a four-wheel drive on a wide, gravel road between Kings Canyon and Hermannsburg in the Northern Territory. McNeilly steered the vehicle to avoid debris on the road then turned sharply the other way while accelerating and rolled the vehicle. Imbree suffered spinal injuries that rendered him a tetraplegic. Imbree brought proceedings against McNeilly and the owner of the vehicle for damages, a sum of $9.5 million was awarded at trial, reduced by 30% on account of contributory negligence. On appeal, the New South Wales Court of Appeal found that McNeilly had not breached his duty of care, applying *Cook v Cook*,[402] and increased contributory negligence to two-thirds. Imbree was granted special leave to appeal to the High Court arguing that McNeilly should be held to have owed him the same objective standard of care as a licensed driver.

The difficulty for the High Court in *Imbree* was the necessity to decide whether, in keeping with *Cook v Cook*, the learner driver owed a different standard of care to the instructing passenger than the standard of care owed to everyone else in the car and around the car. Knowledge of the instructing passenger that the driver was inexperienced was the basis of earlier decisions for asserting that by placing him or herself knowingly in a dangerous situation, a lower standard of care is to be applied. It is the court's discussion of the factors that impact on deciding what standard of care is to be applied in a negligence matter that assists in assessing the appropriate standard of care for a defendant who has a neural interface device. It is not suggested, however, that the person with a neural interface device is equivalent or analogous to an inexperienced driver. It is simply the analysis conducted by the High Court that provides a methodology that assists with the determination of any standard of care.

[401] (2008) 236 CLR 510.

[402] *Cook v Cook* (1986) 162 CLR 376.

When determining the standard of care owed by the learner driver, Gummow, Hayne and Kiefel JJ considered the following principles:

1. The standard to be applied is objective. It does not vary with the particular aptitude or temperament of the individual;[403]

2. The learner driver owes a duty of care to all other road users that requires the learner to meet the same standard of care as any other driver on the road. The learner will be held to the same standard of care as any other driver in fulfilling the learner's duty to take reasonable care to avoid injuring other road users;[404] and

3. Knowledge of inexperience provides no sufficient foundation for applying different standards of care in deciding whether a learner driver is liable to one passenger rather than another. It is not disputed that the learner driver owes each of those persons a standard of care determined by reference to the reasonable driver.[405]

When applying these principles to a person with a neural interface device, the first principle will be complied with if the standard of care is to be that of the reasonable person of ordinary prudence, with the same neural interface device in the same, or similar, circumstances, and this is to be applied objectively without reference to the individual's aptitude or temperament.

In relation to the second principle, when looking at a person with a neural interface device, the other people with whom they are to have the same standard of care are not every other physically able person, but only those who have a similar neural interface device. The neural interface device is not equivalent to a car, it is not a "tool" in the same way that a car is disconnected and separate from the driver. Those individuals with a neural interface device are not "driving the neural interface device" in the same way as the learner driver is "driving the car". It is the *functioning* of the neural interface system – the brain, the neural processor and the device – that is to be compared with that of an able person with no neural interface device. It is the ability of the person to act in unison with the neural interface device that will determine the appropriate standard of care that the defendant with a neural interface device owes to the public, regardless of what task is being undertaken, be it driving a car, building

[403] *Imbree v McNeilly* (2008) 236 CLR 510, 528 [53].
[404] Ibid.
[405] Ibid [54].

a house, transplanting a kidney or any other task chosen. For example, as a driver of a car, the standard of care would be that of a reasonable driver with the same, or similar, neural interface device in the same, or similar, circumstances.[406]

The courts have not applied a different standard of care for people who have psychological or emotional infirmities.[407] The court will not apply a standard of care of a person suffering from that particular mental illness but will apply the objective standard expected of the ordinary person.[408]

> Whilst a child's actions in a negligence claim can be judged by the objective standard to be expected of an ordinary reasonable child of comparable age, the action of an adult lacking capacity because of mental illness in a negligence claim cannot be similarly judged by any objective standard of an ordinary reasonable person suffering from the mental illness; if the mental illness has deprived the person of capacity then the person has also been deprived on rationality and reasonableness. The standard of care must be the objective standard expected of the ordinary person.[409]

However, in situations where a person is physically handicapped, the courts have, in assessing contributory negligence, applied the standard of what can be expected from a reasonably prudent person suffering from this disability.[410] The reasons for this variation are not particularly clear but Moran introduces Oliver Wendell Holmes Junior's argument that distinct physical defects, such as blindness and youth, enable the public to recognise that certain precautions are impossible so adjustments to the reasonable person may be required.[411] In *South Australian Ambulance Transport Inc v Walhdeim*,[412] the hearing of the plaintiff, who was driving a car that was hit by an ambulance, was defective and the plaintiff was acquitted of contributory negligence in failing to hear the ambulance siren. Despite this different standard of care, 'the defendant may have to take correspondingly greater precautions in other respects to compensate for it'.[413] The test of reasonable care in these

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[406] Ibid 521 [27].

[407] *Adamson v Motor Vehicle Trust* (1957) 58 WALR 56; Carrier v Bonham [2002] 1 Qd R 474. See also above under the heading '*1* Standard of Care'.

[408] *Carrier v Bonham* [2002] 1 Qd R 474, 480 [8] (McMurdo P).

[409] Ibid.

[410] Sappideen and Vines above n 370, [7.70].

[411] Moran, above n 371, 138.

[412] *South Australian Ambulance Transport Inc v Walhdeim* (1948) 77 CLR 215.

[413] Sappideen and Vines above n 370, [7.70].

situations 'may depend on whether the defendant … embarked upon a task demanding alertness having regard to what he or she knew or ought to have known about the disability'.[414] However, at the time of this case, contributory negligence was a complete defence at common law. Contributory negligence is no longer a complete defence as apportionment legislation requires the courts to consider what is just when attributing liability for contributory negligence.[415]

There have been cases where physical disability has not afforded any differing of the standard of care.[416] However, in the Western Australian Court of Appeal decision, *Town of Port Hedland v Hodder (No 2)*, Martin CJ stated that the plaintiff's visual impairment was to be taken into account when determining contributory negligence.[417] McLure P found that the plaintiff's visual impairment did not alter the standard of care.[418] The case involved a 22 year old plaintiff, Mr Reece Hodder, who was profoundly deaf, practically blind, virtually unable to speak and suffered from spastic diplegia, became a quadriplegic after diving into the shallow end of a swimming pool in an aquatic centre.[419] The trial judge had concluded that he was bound by authority to assess whether Mr Hodder was contributory negligent by failing to take adequate care for his own safety on an entirely objective basis, that is, without regard to Mr Hodder's various disabilities.[420]

> Mr Hodder had sufficient visual acuity to make out the diving blocks, but insufficient to know the depth of the water in the pool. He had no way of knowing whether he was at the shallow end or the deep end of the pool, or even that there was a shallow end or a deep end. When

[414] Stickley, above n 369, 247 [11.12].

[415] For contributory negligence for tortfeasors contribution and contributory negligence: *CLWACT* s 102(1); *Law Reform (Miscellaneous Provisions) Act 1965* (NSW) s 9(1); *Law Reform (Miscellaneous Provisions) Act* 1956 (NT) s 16(1); *Law Reform Act 1995* (Qld) s 10(1); *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 2001* (SA) ss 7(1), (2); *Wrongs Act 1954* (Tas) s 4(1); *WAVIC* s 26(1); *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 1947* (WA) s 4(1).

For contributory negligence for apportionable claims (Does not include a claim arising out of personal injury or by a consumer): *CLWACT* s 107F(1)(a); *Law Reform (Miscellaneous Provisions) Act 1965* (NSW) s 35(1)(a); *Law Reform (Miscellaneous Provisions) Act 1956* (NT) s 13(1)(a), *Law Reform Act 1995* (Qld) s 31; *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 2001* (SA) s 8(2); *Wrongs Act 1954* (Tas) s 43B(1)(a); *WAVIC* s 24AI(1)(a); *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 1947* (WA) s 5AK(1)(a).

[416] For example, *Henderson v Public Transport Commission of New South Wales* (1981) 37 ALR 29, 34 (Gibbs CJ, Murphy and Aickin JJ) where the plaintiff had deficiency with peripheral vision.

[417] *Town of Port Hedland v Hodder (No 2)* (2012) 43 WAR 383; 445 [259]; *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 1947* (WA) ss 4(1), 5AK(1)(a).

[418] *Town of Port Hedland v Hodder (No 2)* (2012) 43 WAR 383; 452 [298]. The majority was Martin CJ and McLure P.

[419] Ibid 389 [1]-[2].

[420] Ibid 389 [5].

> he responded to the invitation to dive from the block, it was reasonable for him to assume that it was safe for him to do so. He had no way of knowing otherwise. Substantially reducing Mr Hodder's damages on the basis that he failed to take reasonable care to avoid an obvious risk of which he knew or ought to have known, when he was induced to think there was no risk and had no way of knowing otherwise, is unjust.[421]

Martin CJ, acknowledging that the trial judge felt bound by authority to assess Mr Hodder's culpability objectively without regard for Mr Hodder's disabilities, described this injustice in the following terms:

> The harshness, injustice and unfairness in this approach is manifest. It assumes a miracle of biblical proportions and requires the court to assess the question of contributory negligence in some parallel universe in which the blind can see, the deaf can hear, the lame can walk or even run, and the cognitively impaired are somehow restored to full functionality.[422]

Martin CJ provided reasons in logic, justice and public policy why different principles should be applied to the assessment of whether a plaintiff has failed to take reasonable care for his or her own safety, as compared to the principles properly applied in assessing whether a defendant is in breach of a duty to take reasonable care to avoid foreseeable injury to others.[423] Martin CJ also considered the Ipp Report[424] in the application of the Civil Liability Legislation[425] and stated:

> … the issue which the panel was addressing was the question of whether some more relaxed standard should be applied to the assessment of the conduct of victims of tort than that which is applied to putative tortfeasors. It follows that the recommendation of the panel to the effect that the same standard should be applied in both negligence and contributory negligence should be construed in that light … the section properly constructed requires that the court determine whether a plaintiff has failed to take reasonable care for his or her own safety by reference to the conduct that might be expected of a reasonable person in the position of the plaintiff, having any physical defects or incapacities suffered by the plaintiff, or if the plaintiff is a child, of the age of the plaintiff, or if the plaintiff is elderly, having regard to the infirmities

[421] Ibid 422-3 [163] (Martin CJ).

[422] Ibid 420 [156] (Martin CJ).

[423] Ibid 421-3 [159]-[164].

[424] [8.6]-[8.13], inclusive and Recommendation 30.

[425] The court was considering *CLAWA* s 5K Standard of Contributory Negligence but did so in the context of the other civil liability legislation *CLANSW* s 5R; *CLAQ* s 23; *CLAS* s 44; *CLAT* s 23; *WAVIC* s 5K; *CLAWA* s 5B. There are no equivalent provisions in the legislation of the ACT or NT.

> that would generally be associated with such an age. The objective nature of the test to be imposed requires the court to exclude from consideration idiosyncrasies of temperament, behaviour or personality.[426]

There is a distinct possibility, therefore, that when the court is determining a negligence matter involving a person with a neural interface device, it will find an attenuated standard of care for this class of persons on the basis of physical disability. In the United States the objective standard of care for a person with a physical disability has been applied, for example, where an employee was blind.[427] Dietrich and Field identify cases where the courts have gone further than Martin CJ in *Hodder* in relation to the standard of care of a plaintiff when determining contributory negligence[428] but warn that allowances for physical disability are unlikely to be applied when determining the standard of care of a defendant. This is based on the fundamental normative distinction between 'a plaintiff whose conduct endangers others, and a plaintiff whose conduct merely endangers herself'.[429]

It could be argued that a person with a neural interface device that cannot interpret neural impulses as accurately as the natural body[430] has a physical impairment, so this authority would support a different standard of care. However, it can also be argued that a person with a neural interface device is not physically handicapped but is different from the reasonable person because the person has replaced the missing or physically impaired limb with a neural interface device and his or her capabilities may be far beyond the person with a physical handicap. The neural interface device remains an artificial limb that is controlled by the human mind and carries with it imperfections. These imperfections could be regarded as a handicap but the artificial limb could also be regarded as simply having different operational mechanics from a biological limb. Regardless of which argument the court finds most convincing, the standard of care will differ from that of a person who does not have a neural interface device as the existence of the neural interface device will be considered.

In determining a breach of this standard, a court will consider whether, as a result of extensive training in the operation of the device by a neural interface device technician, the

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[426] *Town of Port Hedland v Hodder (No 2)* (2012) 43 WAR 383; 435 [215], 439 [232].

[427] *Roberts v State of Louisiana*, 396 So 2d 566 (La, 1981).

[428] Dietrich and Field, above n 384, 637, including *Goldsmith v Bisset [No 3]* (2015) 71 MVR 53.

[429] Ibid 638-9.

[430] Ohnishi, Weir and Kuiken, above n 373, 43.

person will know of the potential risks of the neural interface device not functioning in complete compliance with the neural impulses as intended. The risk may well be regarded as reasonably foreseeable and if determined to be not insignificant, then the person will be expected to take reasonable precautions.[431] Members of the judiciary who participated in the Delphi Method research rated reasonable foreseeability/foreseeable risk of harm in relation to breach of duty of care as third most important legal issue while both legal practitioners and law academics rated it fourth.

In summary, the neural interface device is not a "tool" as the car is, but an integral part of the human body. Similarly, the physically able individuals are "driving" physical limbs, for example, while the person with a neural interface device is "driving" something that is not a physical limb but a substitute. If the standard of care is to be that of the reasonable person of ordinary prudence, with the same neural interface device in the same, or similar, circumstances, and this standard requires the person to meet the same standard of care as any other person with the same neural interface device, this complies with the second principle.

In compliance with principle three, again, this standard of care is determined by reference to the reasonable person with a neural interface device and that same standard of care is owed to everyone. Recognition of a different standard of care for a person with a neural interface device from the person without a neural interface device would have further support. In *Imbree*, Gummow, Hayne and Kiefel JJ considered circumstances where the common law recognises a different standard of care to be applied.[432] This is where the standard of care expected of a person or activities is required to exercise a standard of care different from, or more particular than, that of some wholly general and objective community ideal. They identified this occurrence amongst professionals such as medical practitioners and specialist medical practitioners. Their Honours also recognised a different standard of care for those at the other end of the spectrum, namely children. They held that in all other cases in which a different level of care is demanded, the relevant standard of care is applied uniformly. No distinction is drawn according to whether the plaintiff was in a position to supervise, even instruct, the defendant although, if the plaintiff was in that position, a failure

[431] *CLANSW* s 5B; *CLAQ* s 9, *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B. See also Stickley, above n 369, 261 [11.46].

[432] Ibid 532 [69].

to supervise or instruct may be of great importance in deciding whether the plaintiff was contributorily negligent.[433]

As was determined by the court:

> No amount of supervision or instruction can alter two facts:
>
> 1. Unless the vehicle has been specially modified to permit dual control, it is the learner driver, not the supervisor or instructor, who operates the vehicle; and
> 2. The skill that is applied in operating the vehicle depends entirely upon the aptitude and experience of the learner driver.[434]

This is not the case with respect to the person with a neural interface device. That person is not instructing or supervising the device in the same way as the instructing driver may be supervising the learner driver, as they are operating the device and it is their aptitude and experience upon which the device is operated. Demonstration of relevant ability, however, is beside the point. What is at issue is the definition of a standard of reasonable care, not any external recognition of attaining an ability to operate the device in accordance with that standard.

Even if the individual was required to hold a licence to certify proficiency in operating the neural interface device,[435] for the same reasons as the court held in *Imbree*, to describe the relevant comparator as a "licensed person" diverts attention from the central inquiry: What would a reasonable person with a neural interface device do? Being authorised by the applicable law to have a neural interface device and move freely with the public is neither a necessary nor a sufficient characteristic of the reasonable person with a neural interface device. The reasonable person with a neural interface device is to be identified by what such a person would do or not do when acting with a neural interface device, not by what authority a person would need to have in order to lawfully be with the public.[436]

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[433] Ibid.

[434] Ibid 532 [66].

[435] See discussion above under the heading '*2* Training and Expertise'.

[436] Ibid 530 [58].

The courts will consider these issues in determining a negligence action where the defendant has a neural interface device and the written judgments will guide re-evaluation and adaptation of the current law. When discussing the reasons for written judgments, Justice Susan Kiefel stated:

> The High Court, as the highest appellate court and constitutional court, has other dimensions to its role. The reasons for judgment of the court may need to explain a further step taken in the development of the law or, in a novel case, the development of the law and the statement of principle being the province of the court.[437]

Not only will future judgments influence the adaptation of the current law, but the courts maintain judicial independence from the legislature and executive branches of government and this separation of power ensures the judiciary interprets and applies the law without intimidation.[438] Sir Anthony Mason further defined the independent judiciary:

> Now the concept has wider scope and includes independence from media and other external "threats". Institutional independence of courts is challenged by reliance on funding from government for the operation of the courts. Depriving a court of its funding could be a serious threat to judicial independence as changing judicial remuneration. Judicial independence can mean many things, including not influenced by others, this is the more common definition now. The object of judicial independence is to preserve impartiality, free from partisanship and ideological commitment.[439]

However, independence within the judiciary can have adverse outcomes. For example:

> Concurring majority judgments raise a harder problem. Those which are not merely repetitive may introduce reasoning not found in the main judgment and may omit reasoning which is found in the main judgment, thus tending to make it harder to find out what the ratio decidendi is.[440]

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[437] Justice Susan Kiefel, 'Reasons for judgment: objects and observations' (Speech delivered at the Sir Harry Gibbs Law Dinner, Emmanuel College, University of Queensland, 18 May 2012) 3 <http://www.hcourt.gov.au/assets/publications/speeches/current-justices/kiefelj/kiefelj-2012-05-18.pdf>.

[438] Anthony Mason, 'Judicial Independence' (Paper presented at the Judicial Independence in Australia Conference, TC Beirne School of Law, University of Queensland, 10 July 2015) <https://www.ruleoflaw.org.au/judicial-independence-australia/>.

[439] Ibid.

[440] Dyson Heydon, 'Threats to Judicial Independence – The Enemy Within' (2013) 129 *Law Quarterly Review* 205, 211.

While there is strong pressure for single majority judgments, Heydon J warned of the possible infringement of judicial independence within the judiciary if single majority judgments and restrictions on the provision of dissenting judgments were pursued.[441]

> Thus, dissenting judgments do not create uncertainty. Nor do separate majority judgments so long as a ratio decidendi among the majority can be discerned. The main source of uncertainty is discordant dicta among members of the majority, or succeeding majorities. The solution is not to shun dissent or multiple majority opinions. It is to minimise dicta of all kinds.[442]

Therefore, judicial independence enables judges to address any uncertainty in the application of the law that will rise when considering alleged negligence of a person with a neural interface device. The High Court has displayed its willingness to change the law when it determined that the standard of care of a learner driver to the instructing passenger is the same, not different from, the standard to be achieved to ensure the safety of any other passenger.[443]

In addition to these principles, the following issues could be considered in determining the appropriate standard of care if a matter came before the courts where the defendant was a person with a neural interface device.

(a) Skill or Knowledge of the Defendant.

As discussed above,[444] it could be argued that the defendant requires skill or knowledge to operate the neural interface device. This could result in a different standard of care from that of a person without a neural interface device in the same circumstances. The skill or knowledge of the person with the neural interface device will influence the probability that the harm would occur if care were not taken and the burden of taking precautions to avoid the risk of harm, both of which the court will consider when determining breach of the duty of care.[445] Factors that will be of significant influence in the court's determination of the

[441] Ibid 211-213.
[442] Ibid 213.
[443] *Imbree v McNeilly* (2008) 236 CLR 510.
[444] Under the heading '*2* Training and Expertise'
[445] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B.

appropriate standard of care to be applied to a defendant who has a neural interface device in relation to skill or knowledge include the following:

1. To operate the neural interface device, the defendant will gain skill or knowledge through training by medical physicians, occupational therapists, physiotherapists, psychologists and neural interface device technicians on the procedures necessary to achieve the desired reaction by the neural interface device. Just as a child learns to walk and interact physically in the world, the defendant will also learn to operate the neural interface device and develop competence in the skills necessary to interact with the world around them.

2. Despite the training undertaken by the defendant, there will remain a degree of uncertainty as to how, or if, the device will respond or operate in accurate compliance with the neural impulses.

3. There will be an inability to anticipate reflex reactions by the neural interface device and this links in with sane automatism.[446]

While it is difficult to conclude what standard of care the court will establish, that standard of care of a person with a neural interface device will be different from an individual without a neural interface device in the same circumstances as the special skill or competence in operating the neural interface device will impact on the standard of care applied.[447]

(b) Policy Considerations

Any social utility of the arguably risk-creating activity will need to be considered by both government and the courts to enable an appropriate balance between public benefit of neural interface devices and public risk.[448] The legislature in each State or Territory could

[446] See analysis under the heading '*2* Neural Interface Device Beyond Being a Tool'.

[447] *Rogers v Whitaker* (1992) 175 CLR 479, 487 cited the following cases as authority: *Cook v Cook* (1986) 162 CLR 376, 383-384; *Papatonakis v Australian Telecommunications Commission* (1985) 156 CLR 7, 36; *Weber v Land & Business Agents Board* (1986) 40 SASR 312, 316; *Lewis v Tressider Andrews Associates Pty Ltd* [1987] 2 Qd R 533, 542.

[448] Social utility of a defendant's conduct has been considered by the court since the introduction of the Civil Liability Legislation. The court has found the following conduct to be of social utility: Attending football matches (*Harris v Bulldogs Rugby League Club Ltd* (2006) Aust Torts Reports ¶81-838), floor to ceiling glass plate window (*Bader v Jelic* [2011] NSWCA 255), physical exercise (*Wilson v Nilepac Pty Ltd (t/as Vision Personal Training (Crows Nest))* [2011] NSWCA 63 and sheep shearing (*Hill v Richards* [2011] NSWCA 291).

amend the Civil Liability Legislation to include factors that need to be taken into account in determining the standard of care, such as physical impairment. The legislation could also require a person with a neural interface device to acquire compulsory third party liability insurance.[449] While such legislative amendments might be considered unlikely, these changes could be influenced by policy considerations such as the State or Territory government's political initiatives which might be driven by both public and commercial interests in the use of neural interface devices.[450] While legislative action in this area of innovation is possible, the complexity of a civil action where a party has a neural interface devices is such that standard of care and the factors to be considered in relation to breach of duty of care may be better addressed by the courts.

Policy considerations, such as indeterminate liability[451] and coherence of the law[452] have been considered by the court in relation to the finding of a duty of care and the scope of that duty.[453] These and other policy factors could be used by the court in determining the scope of the duty of care owed by the individual with a neural interface device and this could influence the standard of care and consequently breach of the duty of care. This will be important in ensuring that liability in negligence of a person with a neural interface device does not extend beyond that of a person without a neural interface device and that judicial decisions in these types of actions do not undermine the coherency of the law.

It is unlikely that the scope of the duty of care for a person with a neural interface device will differ from a person without such a device. However, these policy factors may differ between

[449] See discussion under the heading '*2* Compulsory Third Party Insurance' regarding Kirby J's reference to compulsory third party liability insurance in *Imbree*.

[450] Tony Brown, 'Legislative Capture: A Critical Consideration in the Commercial Determinants of Public Health' (2019) 26 *Journal of Law and Medicine* 764, 766.

[451] Where the court is reluctant to find the existence of a duty of care when it is uncertain of the extent of the liability for the duty of care will extend. This has been expressed as 'in an indeterminate amount for an indeterminate time to an indeterminate class' in *Ultrameres Corp v Touche* 174 NE 441, 444 (1931). Indeterminate liability has been considered in many cases including *Caltex Oil (Australia) Pty Ltd v The Dredge 'Willamstad'* (1976) 136 CLR 529, *Hill v Van Erp* (1997) 188 CLR 159, *Hardie Finance Corporation Pty Ltd v Ahern (No 3)* [2010] WASC 403 and *Carey v Freehills* (2013) ALR 445.

[452] Where the court is reluctant to find the existence of a duty of care when it would interfere with the coherency of the law, that is, 'the need to preserve the coherence of other legal principles, or of a statutory scheme which governs certain conduct or relationships' as stated in *Sullivan v Moody* (2001) 207 CLR 562, 580 [50] (Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ) when referring to *Hill v Van Erp* (1997) 188 CLR 159, 231 (Gummow J). Coherency of the law has been considered in other cases including *Tame v New South Wales* 211 CLR 317 and *Hunter and New England Local Health District v McKenna; Hunter and New England Local Health District v Simon* (2014) 253 CLR 270.

[453] In addition to the cases provided in the previous two footnotes, other cases where policy considerations have been considered by the court include *Tepko Pty Ltd v Water Board* (2001) 206 CLR 1, *Gifford v Strang Patrick Stevedoring* (2003) 214 CLR 269 and *Koehler v Cerebos (Australia) Limited* (2005) 222 CLR 44 .

each member of the bench, as was the case in *Cattanach v Melchior*,[454] so uncertainty in the scope of liability owed by an individual with a neural interface device will be addressed by the courts over time.

Similar findings have occurred in the United States where, for example, the court in *Galindo v TMT Transport, Inc.*[455] stated that the public is best served by applying the reasonable person standard of care to the facts of each case, rather than by fashioning various subjective tests to determine in retrospect what standard of care should have been applied to the facts and circumstances of each case.[456] The *Restatement (Third) of Torts* §11(c)[457] confirms this but exceptions exist where, for example, a person who experienced sudden hallucinations while driving was found to owe a different standard of care from the reasonable prudent person.[458] Decisions in the Canadian courts have gone in both directions. For example, the Alberta Court of Appeal in *Wenden v Trikla*[459] found the standard of care of a reasonable person applied to a person with a psychiatric condition but the courts decided differently in *Buckley v Smith Transport*,[460] *Hutchings v Nevin*,[461] *Attorney-General of Canada v Connolly*[462] and *Fiala v Cechmanek*.[463]

The uncertainty of legislative intervention in influencing the standard of care or breach of the duty of care of a person with a neural interface device will be determined in the future. Likewise, the possibility of the courts deciding on the scope of duty of care by including policy considerations such as indeterminate liability and coherence of the law, is yet to be determined. However, it is unlikely that amendment of the Civil Liability Legislation will occur unless inconsistency in court decisions arise. This could be as a result of uncertainty by members of the judiciary in relation to the interpretation and application of the Civil Liability Legislation. Amendment of the Civil Liability Legislation might also occur if the application of the current law produces results that raise public pressure on politicians to effect a change.

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[454] (2003) 215 CLR 1. Six separate judgments were delivered: Gleeson CJ, McHugh and Gummow JJ, Kirby J, Callinan J, Hayne J (dissenting) and Heydon J (dissenting).

[455] 152 Ariz. 434, 733 P.2d 631, 633.

[456] American Law Institute, *Restatement (Second) of Torts* §283, 20-21.

[457] American Law Institute, *Restatement (Third) of Torts, Liability for Physical and Emotional Harm* (American Law Institute, 2012).

[458] *Breunig v. American Family Insurance Co*., 45 Wis.2d 536, 173 N.W.2d 619 (1970).

[459] (1993) 14 CCLT (2d) 225 (Alberta CA).

[460] [1946] 4 DLR 721 (Ontario CA).

[461] (1992) 12 CCLT 259 (Ontario General Division).

[462] (1989) 64 DLR (4th) 84 (SC).

[463] (2001) 201 DLR (4th) 680 (Alberta CA).

Likewise, policy considerations will assist the court to ensure the scope of duty of care of a person with a neural interface device does not differ from that of a person without such a device.

(c) Perceived Differences from a Person Without a Neural Interface Device.

Whether or not another person can recognise that the defendant has a neural interface device, the person with the neural interface device is expected and required to use due care and diligence. Members of the public could expect that the neural interface device is equivalent to a natural arm but this is not the case.[464] This needs to be recognised when determining the appropriate standard of care as this could be different from the standard of care of a person in the same circumstances without a neural interface device.

4 *Whether the Inference of Negligence (res ipsa loquitur) Applies*

Recognising the complexity of the science behind the integration of mind and machine, outlined in chapter 2, it could be argued that a person with a neural interface device is ”an accident waiting to happen”. *Res ipsa loquitur*, ‘the matter speaks for itself’, is a legal maxim for ‘those special cases in which mere proof of an occurrence causing injury itself constitutes prima facie evidence of negligence.’[465]

The maxim applies when the exact sequence of events leading to the accident is unclear or is not capable of proof.[466] Evidence or common knowledge must establish that such an accident is unlikely to occur without negligence on the part of the defendant.[467]

In *Schellenberg v Tunnel Holdings*, Gleeson CJ and McHugh J stated that the authorities make it clear that:

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[464] Ohnishi, Weir and Kuiken, above n 373, 43.

[465] *Mummery v Irvings Pty Ltd* (1956) 96 CLR 99, 112-117 [15]-[19] (Dixon CJ, Web, Fullagar and Taylor JJ). Their Honours discuss the application of this concept stating, at 114 [16] that it is a ‘general index to those special cases in which mere proof of an occurrence causing injury itself constitutes prima facie evidence of negligence’.

[466] *Anchor Products Ltd v Hedges* (1966) 115 CLR 493, 500 (Windeyer J).

[467] *Piening v Wanless* (1968) 117 CLR 498, 508 (Barwick CJ).

> A plaintiff may rely on *res ipsa loquitur* even though he or she has also pleaded particular acts or omissions of negligence on the part of the defendant provided that the tribunal of fact concludes that:
>
> 1. there is an "absence of explanation" of the occurrence that caused the injury;
> 2. the occurrence was of such a kind that it does not ordinarily occur without negligence; and
> 3. the instrument or agency that caused the injury was under the control of the defendant.[468]

If the plaintiff pleads *res ipsa loquitur,* legal onus is not placed on the defendant to disprove the plaintiff's claim,[469] but adverse inferences might be drawn as a result.[470] The onus remains on the plaintiff to provide evidence of negligence[471] or 'evidence from which negligence may be inferred'[472] and 'it is always necessary that the accident be of a kind which does not ordinarily occur without negligence'.[473]

In Canada, *res ipsa loquitur* had become regarded as a separate component in negligence actions until the decision of the Supreme Court of Canada in *Fontaine v British Columbia (Official Administrator).*[474] The judgment of the Court was delivered by Justice Major who stated that the appeal provided an opportunity for the Court 'to consider the so-called maxim of *res ipsa loquitur*. What is it? When does it arise? And what effect does its application have?'[475]

After considerable analysis, the Court concluded:

> Whatever value *res ipsa loquitur* may have once provided is gone. Various attempts to apply the so-called doctrine have been more confusing than helpful. Its use has been restricted to cases where the facts permitted an inference of negligence and there was no other reasonable explanation for the accident. Given its limited use it is somewhat meaningless to refer to that use as a doctrine of law.

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[468] (2000) 200 CLR 121, 134 [25].

[469] *Davis v Bunn* (1936) 56 CLR 246; *Fitzpatrick v Walter E Cooper Pty Ltd* (1936) 54 CLR 200; *Mummery v Irvings Pty Ltd* (1956) 96 CLR 99. In Canada, this was stated in *Fontaine v British Columbia (Official Administrator)* [1998] 1 SCR 424, 426 [23] (Major J).

[470] Stickley, above n 369, 286 [11.104].

[471] *Hampton Court Ltd v Crooks* (1957) 97 CLR 493.

[472] *Railway Commissioner v Corben* [1939] SR (NSW) 55. See also Stickley, above n 369, 286 [11.106].

[473] Stickley, above n 369, 286 [11.107].

[474] [1998] 1 SCR 424.

[475] *Fontaine v British Columbia (Official Administrator)* [1998] 1 SCR 424, 426 [1].

> It would appear that the law would be better served if the maxim was treated as expired and no longer used as a separate component in negligence actions. After all, it was nothing more than an attempt to deal with circumstantial evidence. That evidence is more sensibly dealt with by the trier of fact, who should weigh the circumstantial evidence with the direct evidence, if any, to determine whether the plaintiff has established on a balance of probabilities a *prima facie* case of negligence against the defendant. Once the plaintiff has done so, the defendant must present evidence negating that of the plaintiff or necessarily the plaintiff will succeed.[476]

The circumstance of each case must be considered before a determination of negligence can be made, despite the plaintiff pleading *res ipsa loquitur*.[477] 'Where there is direct evidence available as to how an accident occurred, the case must be decided on that evidence alone.'[478] In this way, the application of *res ipsa loquitur* in Canada is in line with that of Australia, despite the legal maxim continuing to exist in Australia.

In the United States of America, the application of *res ipsa loquitur* is provided in *The Restatement (Third) of Torts*: Liability for Physical and Emotional Harm §17.[479] The Background of the section states:

> *Res ipsa loquitur* is an appropriate form of circumstantial evidence enabling the plaintiff in particular cases to establish the defendant's likely negligence. Hence, the *res ipsa loquitur* doctrine, properly applied, does not entail any covert form of strict liability.
>
> Indeed, the availability of *res ipsa loquitur* in one sense weakens the case on behalf of strict liability. One argument favoring strict liability is that the unavailability of evidence in some cases renders the plaintiff unable to establish what may well have been the defendant's actual negligence. By providing the plaintiff in such cases with an alternative method of proving the defendant's negligence, *res ipsa loquitur* reduces the need for strict liability.
>
> However, *res ipsa loquitur* is circumstantial evidence of a quite distinctive form. The doctrine implies that the court does not know, and cannot find out, what actually happened in the individual

[476] Ibid 435 [26]–[27].
[477] Ibid 426 [20].
[478] Ibid 426 [21].
[479] Chapter 3 The Negligence Doctrine and Negligence Liability, §17 *Res ipsa loquitur*.

case. Instead, the finding of likely negligence is derived from knowledge of the causes of the type or category of accidents involved.[480]

In a *res ipsa* case, the jury should be invited to compare those causes of the type of accident that suggest the negligence of the defendant with all other causes (whether negligent or not), and to find in favor of *res ipsa* if the former predominate.[481]

The High Court considered the application of *res ipsa loquitur* in judgments from other jurisdictions and in *Schellenberg v Tunnel Holdings* stated:

> The plaintiff contends that the application of *res ipsa loquitur* has accumulated a number of "encrustations" in the course of its judicial history that have hardened the maxim into a rigid rule of law, when it is merely a factor to be weighed "with the direct evidence to determine whether the plaintiff had established, on a balance of probabilities, a case." The plaintiff urged the Court to follow the Supreme Court of Canada in *Fontaine v British Columbia (Official Administrator)* and abolish the maxim "as a separate component in negligence actions". To do so, it was said, would be "consonant with the steps taken by this court to absorb isolated pockets of technical law into a context appropriate to its original rationale" as this Court did in *Australian Safeway Stores Pty Ltd v Zaluzna* and *Burnie Port Authority v General Jones Pty Ltd*.
>
> In our opinion, this Court should not follow that course. The Court has affirmed time and again that *res ipsa loquitur* is merely a mode of inferential reasoning and is *not* a rule of law. The "encrustations" that the plaintiff alleges do not exist. The fact that a plaintiff falls outside the "proper scope" of the rule does not mean that he or she may not avail himself or herself of inferential reasoning. There is therefore no need to subsume the maxim into the general body of tort law: it is already fully consonant with it. [482]

It appears, therefore, that the use of *res ipsa loquitur* in the United States is similar to its application by the Australian courts. It could be argued that as a result of the inability for the neural interface device to interpret neural impulses as accurately as the natural body,[483] the person with the neural interface device is more likely to make errors that cause damage to

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[480] American Law Institute, *Restatement (Third) of Torts*: Chapter 3 The Negligence Doctrine and Negligence Liability, §17 *Res ipsa loquitur* 1-2.

[481] Ibid 2-4.

[482] (2000) 200 CLR 121, 140-1 [46]-[47] (Gleeson CJ and McHugh).

[483] Ohnishi, Weir and Kuiken, above n 373, 43.

others. As a result, the court will not be required to determine the degree to which the neural interface device and the human body have contributed to the event, suffice to say the combination of both has caused the injury. Therefore, *res ipsa loquitur* could be raised by the plaintiff against a person with a neural interface device on the basis that the damage has occurred as a result of the combined negligence of the person and the neural interface device, without the need to determine the contribution of each. However, *res ipsa loquitur* is unlikely to be pleaded because inferential reasoning would, in most cases, eliminate one of the factors necessary, as outlined above in *Schellenberg v Tunnel Holdings*.[484]

This analysis of the element of breach of duty of care when a person has a neural interface device has identified the possibility that the standard of care expected of a person with a neural interface device will be different from that applied to a person without such a device. The concept of revolutionary science[485] applied to this analysis highlights that recognition by the courts of a different standard of care to be applied to a defendant with a neural interface device than a defendant without the device could be regarded as anomalous to the current law.

D *Causation*

Damage is the gist of negligence,[486] but there can be no liability unless the damage suffered by the plaintiff is caused by the defendant's breach of duty of care. This involves consideration of both factual causation and scope of liability pursuant to the Civil Liability Legislation. For example, in the *CLAQ*:

> **11 General principles**
>
> (1) A decision that a breach of duty caused particular harm comprises the following elements—
>
> (a) the breach of duty was a necessary condition of the occurrence of the harm (***factual causation***);

[484] (2000) 200 CLR 121, 134 [25]. Those necessary factors to enable *res ipsa loquitur* to be pleaded are:

1. there is an "absence of explanation" of the occurrence that caused the injury;
2. the occurrence was of such a kind that it does not ordinarily occur without negligence; and
3. the instrument or agency that caused the injury was under the control of the defendant.

[485] Kuhn, above n 2.

[486] *Harriton v Stephens* (2006) 226 CLR 52, 78 [78] (Kirby J); 102 [161] (Hayne J); 115 [218], 126 [251] (Crennan J).

(b) it is appropriate for the scope of the liability of the person in breach to extend to the harm so caused (***scope of liability***).[487]

Section 11(1)(a) reflects the established principles at common law and application of the 'but for' test[488] while s 11(1)(b) extends the common law concept of remoteness in that, for the purpose of deciding the scope of liability, the court is to consider (among other relevant things) whether or not and why responsibility for the harm should be imposed on the party who was in breach of the duty.[489] In the articulation of causation at common law, 'the distinct nature of these two questions has tended to be overlooked'.[490] 'Causation at law is not so much a question of what caused the plaintiff's loss but what specific conduct (i.e. an act or omission) of the defendant caused that loss.'[491] Both factual causation and scope of liability are discussed below.

In the Delphi Method research conducted and discussed in chapter 3, participants ranked causation 9th most importance out of the 23 legal issues identified by participants. A legal practitioner who participated in the Delphi Method research stated:

> I analyse it in this way. First, if there were perfect translation of the brain's instructions then one would be analysing the issues of any injury scenario in the usual way: primarily negligence and if there was a prosthetic arm by an examination of whether that made any difference. The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation. And of course, difficulties of proof (because the question of whether, and if so, the degree of imperfect translation will be something entirely within the mind of the defendant).

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[487] *CLWACT* s 45; *CLANSW* 5D; *CLAS* s 34; *CLAT* s 13; *WAVIC* s 51; *CLAWA* s 5C. There is no equivalent provision in the Northern Territory.

[488] *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506, 515-9 (Mason CJ).

[489] *CLWACT* s 45(3); *CLANSW* 5D(4), *CLAQ* s 11(4), *CLAS* s 34(3); *CLAT* s 13(4); *WAVIC* s 51(4); *CLAWA* s 5C(4). There is no equivalent provision in the Northern Territory.

[490] Tony Bowen, 'Section 5D of *Civil Liability Act 2002* (NSW): Causation' (Speech delivered 22 March 2017) <http://ebc44.com/wp-content/uploads/2017/06/Bowen_2017_03_22.pdf> 3 [7]; *Wallace v Kam* (2013) 250 CLR 375.

[491] Ibid 2 [5].

'Duty of care is a thing written on the wind unless damage is caused by the breach of that duty: There is no actionable negligence unless duty, breach and consequential damage coincide'.[492]

In addition, in *Roads and Traffic Authority v Royal*,[493] the High Court decided that simply because a risk of harm exists, a failure to fulfil the duty of care is insufficient to establish liability in negligence. The breach of the duty of care must be 'a necessary condition of the occurrence of the particular harm.'[494]

Prior to the introduction of Civil Liability Legislation, Kirby J in *Modbury Triangle Shopping Centre Pty Ltd v Anzil*,[495] said 'causation in fact is a matter to be determined from all of the evidence and the inferences drawn from the evidence. As has been said many times, it is a question that requires the application of common sense'. Professor Jane Stapleton of the Australian National University College of Law, asserts that this 'common sense' causation means the court can 'infer facts from common experience.'[496] However, Stapleton argues that judgments, such as *Roads and Traffic Authority v Royal:*[497]

> highlight the danger of this, in that a court will elide proof of breach … and foreseeable result … with proof that the breach was a factual cause of that result … and fail adequately to consider whether there was, on the evidence, any "sufficient reason to the contrary".[498]

This use of 'common sense principles of causation' was promoted by Hart and Honoré[499] resulting in the blurring of the distinction between factual causation and scope of liability by the judiciary, especially when intervening acts were involved.[500] Stapleton recognises that consequently:

> Some judges will be tempted to present their determinations relating to truncation [scope of liability] without adequate normative justification. Accompanying this is the risk that, so long as

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[492] *John Pfeiffer Pty Ltd v Canny* (1981) 148 CLR 210, 241 (Brennan J).

[493] (2008) 82 ALJR 870.

[494] *Strong v Woolworths* (2012) 246 CLR 182, 191 [20].

[495] (2000) 205 CLR 254, [92] where his Honour cites as authority, *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506 and *Chappel v Hart* (1998) 195 CLR 232, [93].

[496] Stapleton, Jane, 'Factual Causation' (2010) 38(3) *Federal Law Review* 467, 469.

[497] (2008) 82 ALJR 870.

[498] Stapleton, 'Factual Causation', above n 496, 469.

[499] Herbert L A Hart and Tony Honoré, *Causation in the Law* (Clarendon Press, 2nd edition, 1985), 11.

[500] Stapleton, 'Factual Causation', above n 496, 469-70.

> both the factual issue of historical involvement and the normative issue of the truncation of liability are framed as 'causal' questions, a trial judge may not easily recognise whether statements in previous appellate cases concerning 'causation' relate to historical involvement or truncation.[501]

This blurring of the distinction between factual causation and scope of liability was addressed but not resolved by the Ipp Report.[502] Despite the Ipp Report acknowledging a need to clarify causation terminology by separating factual causation and the scope of liability:

> Bizarrely, however, the Ipp Report chose to retain the umbrella term of 'causation' to signify the amalgam of both issues. So it was that, at the very time the American Law Institute was stripping the truncation issue of its misleading causal label throughout the law of torts, the Ipp Report was entrenching that barrier to clarity of legal analysis in Australia: for all Australian States plus the Australian Capital Territory[503] followed the Ipp Report recommendation and legislatively adopted the 'causation' umbrella term albeit only in the limited field covered by that Report, namely where the focus is on the 'fault of a person (the "tortfeasor"),[504] 'negligence'[505] or a 'breach of duty'.[506]

As Stapleton asserts:

> My view is that it is analytically more efficient if a single meaning for the notion of "cause" is adopted throughout the law, one that is a question of fact: In law it should be the case that either a "causal connection" exists between a breach and the result or it does not. This would lessen the second danger because, after resolution of this factual cause question, courts would then need to confront the complex normative issues that affect the "appropriate scope of liability for consequences of breach" without being tempted by the camouflage of vacuous causal assertions. Within this normative step of the analysis would fall the principles, rules and concerns traditionally labelled in terms of "remoteness of damage", "mitigation of damages", "proximate causation" and so on.[507]

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[501] Ibid 471.

[502] Commonwealth of Australia, above n 355, 109 (footnote 6); 117-8 (Recommendation 29).

[503] *CLWACT* s 45; *CLANSW* s 5D; *CLAQ* s 11; *CLAS* s 34; *CLAT* s 13; *WAVIC* s 51; *CLAWA* s 5C. Neither the Northern Territory nor the Commonwealth has implemented any provision relating to 'causation'.

[504] *CLAWA* s 5C(1).

[505] *CLWACT* s 45(1); *CLANSW* s 5D(1); *CLAS* s 34(1); *WAVIC* s 51(1).

[506] *CLAQ* s 11(1); *CLAT* s 13(1); Stapleton, 'Factual Causation', above n 496, 471.

[507] Jane Stapleton, 'Reflections on Common Sense Causation in Australia' in Simone Degeling, James Edelman and James Goudkamp (eds), *Torts in Commercial Law* (Thomsons, 2011) 331, 353.

The solution, suggests Stapleton, is for the Australian courts to quietly ignore the umbrella term both under the Civil Liability Legislation and elsewhere, resist 'the temptation to refer to "common sense causation" and proceed directly to the analysis of the separate issues of factual causation and scope of liability.'[508]

In summary, Stapleton argues for:

> an analytical structure that provides a clear separation between two questions: whether the defendant's breach of the legal rule contributed in any way to the occurrence of the result of which the plaintiff complains (the "factual causation" question); and if so, whether in the context of the relevant legal rule the defendant should be legally responsible for this result of his breach (the normative "scope-of-liability-for-consequences-of breach" question).[509]

Recognising the causation issues raised by Stapleton regarding the blurring of the distinction between factual causation and scope of liability, the following analysis of causation where the defendant has a neural interface device is undertaken.

1 *Factual Causation*

Six participants in the Delphi Method research considered that the issue of factual causation in the damage element of a negligence action against a person with a neural interface device will be of importance. This issue was centred around the technical aspects of the neural interface device and law academic A1 said 'Factual challenges will likely arise in causation' while participant P7 stated, 'The questions of causation are likely to be difficult'. For factual causation to be satisfied under Civil Liability Legislation, the breach of the duty of care by the person with a neural interface device will need to be a necessary condition for the occurrence of the harm through the application of the 'but for' test.[510] For example, *CLAQ* s 11(1)(a) provides that 'the breach of duty was a necessary condition of the occurrence of the harm (***factual causation***).'

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[508] Stapleton, 'Factual Causation', above n 496, 471.

[509] Stapleton, 'Reflections on Common Sense Causation in Australia', above n 507, 350.

[510] *Wallace v Kam* [2012] NSWCA 82, *Strong v Woolworths* (2012) 246 CLR 182, 190 [18] and *Adeels Palace v Moubarak* (2009) 239 CLR 420. Where there are multiple causes *Zanner v Zanner* (2010) 79 NSWLR 702. *CLWACT* s 45, *CLANSW* s 5D, *CLAQ* s 11, *CLAS* s 34, *CLAT* s 13, *WAVIC* s 51 and *CLAWA* s 5C. There is no equivalent provision in the Northern Territory.

In essence, the test establishes whether, "but for" the breach of duty of care of the defendant, the plaintiff would not have suffered the harm.[511] In the context of the person with a neural interface device being a defendant in a negligence action, the test would be applied to the person with the neural interface device but the court would need to determine whether the person's negligence was a necessary condition of the harm.[512] The determination of causation under the legislation 'is nothing more or less than a determination on the balance of probabilities that the harm that in fact occurred would not have occurred absent the negligence'.[513] Proving that it is a necessary condition of the harm is 'entirely factual, turning on proof by the plaintiff of relevant facts on the balance of probabilities'.[514] Where there are a number of circumstances that could have caused the harm, the High Court has recognised that the 'defendant's negligent act or omission which is necessary to complete a set of conditions that are jointly sufficient to account for the occurrence of harm will meet the test of factual causation within' the civil liability provision for factual causation.[515]

The High Court in *Strong v Woolworths*[516] acknowledged *March v Stramare*[517] when considering the statutory statement of the 'but for' test.[518] Despite this, the High Court of Australia, in *Strong v Woolworths*, applied the established principles from *March v Stramare* to the 'but for' test. Prior to the introduction of Civil Liability Legislation, the dangers of applying the 'but for' test with the exclusion of common sense was considered by Mason CJ

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[511] 'The determination of factual causation under s 5D(1)(a) is a statutory statement of the "but for" test of causation: the plaintiff would not have suffered the particular harm but for the defendant's negligence.' In *Strong v Woolworths* (2012 246 CLR 182, 190 [19] (French CJ, Gummow, Crennan and Bell JJ).

[512] *Strong v Woolworths* (2012) 246 CLR 182, 191 [20].

[513] *Wallace v Kam* (2013) 250 CLR 375, 383 [16].

[514] Ibid 383 [14].

[515] *Strong v Woolworths* (2012) 246 CLR 182, 191 [20]. The provision referred to in this case was *CLANSW* s 5D(1)(a):

> **5D General principles**
>
> (1) A determination that negligence caused particular harm comprises the following elements:
>
> (a) that the negligence was a necessary condition of the occurrence of the harm (**"factual causation"**), and
>
> (b) that it is appropriate for the scope of the negligent person's liability to extend to the harm so caused (**"scope of liability"**).
>
> Equivalent provisions: *CLWACT* s 45(1)(a), *CLAQ* s 11(1)(a), *CLAS* s 34(1)(a), *CLAT* s 13(1)(a), *WAVIC* s 51(1)(a) and *CLAWA* s 5C(1)(a).

[516] (2012) 246 CLR 182, 190 [18].

[517] (1991) 171 CLR 506, 515-516 (Mason CJ).

[518] For a discussion on the use of the common law 'but for' test in the application of the statutory 'but for' test, see Greg Williams and Sheena McKie, *But for Still a Necessary Condition for Causation* (5 December 2012) <https://www.claytonutz.com/knowledge/2012/december/but-for-still-a-necessary-condition-for-causation>.

in *March v Stramare*.[519] When applying the 'but for' test in circumstances where two or more acts or events would each be sufficient to cause injury to the plaintiff, Mason CJ stated that these circumstances, 'demonstrate the lesson of experience, namely, that the test, applied as an exclusive criterion of causation, yields unacceptable results and that the results which it yields must be tempered by the making of value judgments and the infusion of policy considerations.'[520] Mason CJ said:

> In similar fashion, the "but for" test does not provide a satisfactory answer in those cases in which a superseding cause, described as a *novus actus interveniens*, is said to break the chain of causation which would otherwise have resulted from an earlier wrongful act.[521]

In conclusion, Mason CJ said:

> As a matter of both logic and common sense, it makes no sense to regard the negligence of the plaintiff or a third party as a superseding cause or *novus actus interveniens* when the defendant's wrongful conduct has generated the very risk or injury resulting from the negligence of the plaintiff or a third party and that injury occurs in the ordinary course of things. In such a situation, the defendant's negligence satisfies the "but for" test and is properly to be regarded as a cause of the consequence because there is no reason in common sense, logic or policy for refusing to so regard it.[522]

The High Court in *Strong v Woolworths* restated the two limitations of the 'but for' test:

> First, it produces anomalous results in particular cases, exemplified by those in which there is more than one sufficient condition of the plaintiff's harm. Second, it does not address the policy considerations that are bound up in the attribution of legal responsibility for harm (32).
>
> 32 *Medlin v State Government Insurance Commission* (1995) 182 CLR 1 at 6-7 per Deane, Dawson, Toohey and Gaudron JJ; *Chappel v Hart* (1998) 195 CLR 232 at 255-256 [62]-[63] per Gummow J; *Travel Compensation Fund v Tambree (t/as R Tambree & Associates)* (2005) 224 CLR 627 at 639 [28] per Gleeson CJ; *Roads and Traffıc Authority v Royal* (2008) 82 ALJR 870 at 878 [32]; 245 ALR 653 at 662-663 per Gummow, Hayne and Heydon JJ; at 896; 687 [135] per Kiefel J.[523]

[519] (1991) 171 CLR 506, 515-9.
[520] *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506, 516.
[521] Ibid 517.
[522] Ibid 518-9.
[523] (2012) 246 CLR 182, 190-1 [18] (French CJ, Gummow, Crennan and Bell JJ).

Therefore, when considering factual causation, these limitations also apply to the statutory 'but for' test. To assist, the High Court stated:

> Under the statute, factual causation requires proof that the defendant's negligence was a necessary condition of the occurrence of the particular harm (37). A necessary condition is a condition that must be present for the occurrence of the harm. However, there may be more than one set of conditions necessary for the occurrence of particular harm and it follows that a defendant's negligent act or omission which is necessary to complete a set of conditions that are jointly sufficient to account for the occurrence of the harm will meet the test of factual causation within s 5D(1)(a) (38). In such a case, the defendant's conduct may be described as contributing to the occurrence of the harm.
>
> 37 As McHugh J points out in *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506 at 529-530, the concept of a condition that is necessary to an occurrence is the lawyers' adaptation of John Stuart Mill's theory that the cause of an event is the sum of the conditions which are jointly sufficient to produce it. See also Hart and Honoré, *Causation in the Law*, 2nd ed (1985), pp 68-69, 109-114.
>
> 38 Fleming, *The Law of Torts*, 9th ed (1998), p 219; *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506 at 509 per Mason CJ. See also Hart and Honoré, *Causation in the Law*, 2nd ed (1985), p 18.[524]

Delphi Method research participant, legal practitioner L2, stated that a technical issue of primary importance will be an evaluation of the risk caused by the imperfect translation of the brain's instructions:

> I analyse it in this way. First, if there were perfect translation of the brain's instructions then one would be analysing the issues of any injury scenario in the usual way: primarily negligence and if there was a prosthetic arm by an examination of whether that made any difference. The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation. And of course, difficulties of proof (because the question of whether, and if so, the degree of imperfect translation will be something entirely within the mind of the defendant).

Therefore, to assist with analysis of factual causation, the following scenario is provided.

[524] *Strong v Woolworths* (2012) 246 CLR 182, 191-2 [20]. Section 5D(1)(a) can be viewed at footnote 515 and equivalent provisions are identified.

(a) The Scenario

In the context of an event involving a person with a neural interface device, factual causation will be difficult to determine. For example, a person with neuroprosthetic legs (NID driver) is driving a regular motor car along a side street and fails to stop at an intersection that has a 'Give Way' sign facing the NID driver. As they move through the intersection, a vehicle that has right of way passes in front of the NID driver and the NID driver's car collides with the side of the other car. The NID driver has an established duty of care to drive with due care and attention to avoid harming other drivers or those alongside the road.[525] Failing to give way, together with other factors such as the NID driver acting with regard to the limitations of the neuroprosthetic legs, may enable to the Court to find a breach of the duty of care. For the purposes of discussing causation, it has been determined that the NID driver has breached their duty of care. When it comes to the final element damage, the court will need to determine whether the NID driver's breach was a necessary condition for the harm to have occurred, that is, the harm would not have occurred absent the breach.

If the breach of duty of care of the NID driver is a condition that must be present for the occurrence of the damage to the other car, then it will be a necessary condition that will satisfy the Civil Liability Legislation 'but for' test of causation.[526] However, any of the following may be alleged to have also occurred, in relation to the limitations of neural interface technology as discussed in chapter 2:[527]

- The neural impulse sent from the brain to apply the brakes before the intersection was not detected by the decoder.
- The neural impulse sent from the brain to apply the brakes before the intersection was misinterpreted by the decoder as an instruction to apply the assistive device, that is, the neuroprosthetic leg, to the accelerator.
- The neural impulse sent from the brain to apply the brakes before the intersection was correctly communicated by the decoder to the neuroprosthetic leg but there was

[525] *Edwards v Noble* (1971) 125 CLR 296, *Loveday v Paddison* [1965] Qd R 535, *Manley v Alexander* (2005) 223 ALR 228 and *Imbree v McNeilly* (2008) 236 CLR 510.

[526] *CLWACT* s 45; *CLANSW* s 5D; *CLAQ* s 11; *CLAS* s 34; *CLAT* s 13; *WAVIC* s 51; *CLAWA* s 5C. There is no equivalent provision in the Northern Territory.

[527] See analysis under the heading '*D* Limitations of Neural Interface Device Technology'.

insufficient time for the neuroprosthetic leg to respond before entering the intersection.

- The neural impulse sent from the brain to apply the brakes before the intersection was correctly communicated by the decoder to the assistive device but insufficient pressure was applied to brakes.
- Sensing information sent from the neuroprosthetic leg to the decoder that the neuroprosthetic leg had not made contact with the brake pedal was not communicated to the brain.
- Sensing information sent from the neuroprosthetic leg to the decoder that contact had been made with the brake pedal was communicated to the brain but was misinterpreted by the person as failure to make contact with the brake pedal.
- Sensing information sent from the neuroprosthetic leg to the decoder regarding the pressure being applied to the brake pedal was communicated to the brain but insufficient pressure was applied to brakes.
- Power within the decoder was less than necessary for normal speed of processing and this interfered with the speed of decoding neural impulse, delaying instructions being sent to the neuroprosthetic leg.
- The computing capacity of the neuroprosthetic leg could not enable the device to act as quickly as a biological leg, so the application of pressure to the brake pedal was not as effective.

It could be argued that it is one of these events that satisfies the 'but for' test of factual causation for the harm that occurred and not the breach of the duty owed by the NID driver to the other driver. If this is the case, the complexity of any of these events, incorporating the communication between the human brain and the neuroprosthetic legs, is such that the court will find it extremely difficult to determine whether liability should fall solely on the NID driver, solely on the manufacturer of the neural interface device or shared between the two of them. This dilemma is discussed below under the heading '*3* Liability of Neural Interface Device Manufacturer and the NID Driver'.

However, in relation to factual causation, determination of whether it was an incorrect command from the brain or incorrect decoding of the neural impulse, will also be incredibly difficult for the court to determine. The court will look at the actions of the defendant and what a reasonable person in the position of the defendant would have done. Intention of the

defendant does not play a role but in these circumstances, the command from the brain needs to be known to determine what happened and who should be liable. Several problems may exist in relation to the scenario above, including the defendant asserting that the command was to apply the brake but the neuroprosthetic leg did not do that or did not apply the brake with the force intended by the command. If the decoder records show that the command was not what the defendant says it was, who is the court to believe? To what extent will the evidence of the decoder be admissible? If the decoder records are admissible, what probity will be applied to that evidence? Chapter 6 briefly discusses this evidentiary dilemma.[528]

As discussed in chapter 2,[529] the decoding of neural impulse is extremely complicated and not 100 per cent accurate. In addition, the knowledge of how the human brain functions is still being acquired, so it is arguable that the science enabling the melding of mind and machine is not completely understood and the court may be unable to disentangle the specific roles the individual and the neural interface device played in causing the car accident. As a result of the difficulty in determining exactly what occurred in the communication between the mind and the neural interface device, it might be argued that this creates an evidentiary gap that precludes the NID driver's negligence in relation to an accident from satisfying the 'but for' test of causation. This evidentiary gap may give rise to what has been recognised in tort law as an exceptional case, as provided for in Civil Liability Legislation.[530]

Referring to the Ipp Report, the majority in the High Court decision, *Strong v Woolworths*,[531] stated the circumstances in which an exceptional case might arise:

> The Ipp Report instanced two categories of such cases. The first category involves the cumulative operation of factors in the occurrence of the total harm in circumstances in which the contribution of each factor to that harm is unascertainable.[532] *Bonnington Castings*[533] was

[528] See chapter 6 under the heading '3 Neuroscientific Evidence' located under the heading '*G* Further Research Opportunities'.

[529] See analysis under the heading '*D* Limitations of Neural Interface Device Technology'.

[530] *CLWACT* s 45(2), *CLANSW* s 5D(2), *CLAQ* s11(2), *CLAS* s 34(2), *CLAT* s 13(2), *WAVIC* s 51(2), *CLAWA* s 5C(2) provide for tests other than the 'but for' test but do not call these exceptional cases. There is no equivalent provision in the Northern Territory.

[531] (2012) 246 CLR 182, 194 [25] (French CJ, Gummow, Crennan and Bell JJ).

[532] Ipp Report, 109 [7.28].

[533] [1956] AC 613 but the citation for this case was not footnoted in this paragraph of the judgment.

said to exemplify cases in this category. The second category involves negligent conduct that materially increases the risk of harm in circumstances in which the state of scientific or medical knowledge makes it impossible to prove the cause of the plaintiff's harm.[534] *Fairchild v Glenhaven Funeral Services Ltd*[535] was said to exemplify cases in this category.

The majority[536] then discussed material increase in risk and materially contributes:

> Whether negligent conduct resulting in a material increase in risk may be said to admit of proof of causation in accordance with established principles under the common law of Australia has not been considered by this Court.[537] Negligent conduct that materially contributes to the plaintiff's harm but which cannot be shown to have been a necessary condition of its occurrence may, in accordance with established principles,[538] be accepted as establishing factual causation, subject to the normative considerations to which s 5D(2) requires that attention be directed.[539]
>
> In some cases, although the relative contribution of two or more factors to the particular harm cannot be determined, it may be that each factor was part of a set of conditions necessary to the occurrence of that harm.[540]

In relation to the first category of exceptional cases and the damage to the car by the NID driver, it is feasible that the individual contribution of the human neural impulses and the neural interface device is unascertainable. This outcome is caused by the difficulty in

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[534] Ipp Report, 110 [7.30].

[535] [2003] 1 AC 32.

[536] French CJ, Gummow, Crennan and Bell JJ.

[537] *Amaca Pty Ltd v Ellis* (2010) 240 CLR 111 at 123 [12]; *Roads and Traffic Authority v Royal* (2008) 82 ALJR 870 at 888-889 [94]; 245 ALR 653 at 677 per Kirby J.

[538] *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506 at 514 per Mason CJ.

[539] *Strong v Woolworths* (2012) 246 CLR 182, 194 [26]. *CLANSW* s 5D(2) states:

> (2) In determining in an exceptional case, in accordance with established principles, whether negligence that cannot be established as a necessary condition of the occurrence of harm should be accepted as establishing factual causation, the court is to consider (amongst other relevant things) whether or not and why responsibility for the harm should be imposed on the negligent party.
>
> (3) If it is relevant to the determination of factual causation to determine what the person who suffered harm would have done if the negligent person had not been negligent:
>
> (a) the matter is to be determined subjectively in the light of all relevant circumstances, subject to paragraph (b), and
>
> (b) any statement made by the person after suffering the harm about what he or she would have done is inadmissible except to the extent (if any) that the statement is against his or her interest.

Equivalent provisions: *CLWACT* s 45(2), *CLAQ* s 11(2), *CLAS* s 34(2), *CLAT* s 13(2), *WAVIC* s 51(2) and *CLAWA* s 5C(2).

[540] *Strong v Woolworths* (2012) 246 CLR 182, 194 [27].

determining exactly what occurred in the communication between the brain and the neural interface device.

In relation to the second category of exceptional cases, the negligent conduct of either the NID driver failing to send the correct command to the neural interface device or incorrect instructions being sent from the neural processor to the neuroprosthetic leg, it is possible that the present state of scientific or medical knowledge makes it impossible to prove which of the two acts caused the damage to the plaintiff's vehicle.

Alternatively, in circumstances where 'the damage is the result of the simultaneous operation of two or more separate and independent events each of which was sufficient to cause the damage',[541] the 'but for' test is replaced with a sufficiency requirement.[542] In these circumstances 'it may sometimes be helpful for courts or commentators to be able to refer to an algorithm that represents the notion of contribution. The act or occurrence being considered 'contributes to the outcome if it is a Necessary Element for the Sufficiency of a Subset of the facts.'[543] This is known as the NESS test'.[544] If the 'but for' test cannot be applied to the circumstances involving a person with a neural interface device, the NESS test could be used. For example, in *South Australia v Ellis*,[545] Steytler P and McLure JA of the Western Australia Court of Appeal stated:

> Thus, a contribution is material if it is something more than de minimis. It follows that satisfaction of the 'but for' test of factual causation is not required when a factor makes a material cumulative contribution to the contraction of an indivisible disease. Neither does the 'but for' test apply to multiple sufficient causes. Moreover, a material cumulative contribution does not cease to be such simply because another contributing factor was itself sufficient and would have caused the disease.

[541] *March v Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506, 534 (McHugh J).

[542] David Hamer, 'Mind the "Evidential Gap": Causation and Proof in *Amaca Pty Ltd v Ellis*' (2009) 31 *Sydney Law Review* 465, 476.

[543] Ibid 479.

[544] Stapleton, 'Factual Causation', above n 496, 479.

[545] (2008) 37 WAR 1, [309].

Steytler P and McLure JA disagreed with the dissenting judgment of Martin CJ, stating:

> We also respectfully disagree with the view of the Chief Justice that if Mr Cotton would have suffered lung cancer irrespective of the consequences of the appellants' breaches of duty in exposing him to asbestos, it cannot be said the breaches relating to asbestos materially contributed to Mr Cotton's disease. First, it is inconsistent with the conventional principle of common law causation that a breach can materially contribute to an outcome notwithstanding there are other sufficient causes of that outcome. Secondly, it is inconsistent with the conventional principle that conduct which accelerates the contraction of a disease materially contributes to that outcome.[546]

As the operation of the neural interface device is not independent of the neural impulse from the brain, the actions of both the person and the neural interface device contribute to the outcome so it is unlikely the NESS test will be required. However, whether or not communication between the mind and neural interface device could be regarded as an intervening act could also be considered. If it was established that the NID driver sent a neural command to the decoder to instruct the neuroprosthetic leg to apply the brakes but the pressure applied to the brake was not adequate to stop the vehicle, then both events have contributed to harm. However, if the decoder misinterpreted the neural command and instructed the neuroprosthetic leg to apply pressure to the accelerator instead of the brake, it could be argued that the actions of the decoder and neuroprosthetic leg were intervening acts that break the chain of causation between the person's neural actions and the harm.

However, there would be difficulty sustaining such an argument for the reasons discussed above regarding factual causation, that is, the inability of the evidence to fully distinguish between the command from the brain and the decoding of the command. For this reason and the fact that the neural interface device is so fully integrated with the human body, the court is unlikely to regard the operation of the neural interface device as being an intervening act or omission. The action of the neural interface device was not voluntary, deliberate or negligent but based on the command from the human brain. 'A supervening act which breaks the chain of causation must be a separate and independent act which intervenes after the negligent conduct complained of.'[547] The action of the neural interface device is not subsequent to the NID driver's negligence, but intimately connected to it.

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[546] *South Australia v Ellis* (2008) 37 WAR 1, [233].

[547] Ibid 1 [324] (Staytler P and McLure JA).

In addition, it might also be the case that the action of the neural interface device is a reasonably foreseeable consequence of the NID driver's negligence. The NID driver's negligence could be as a result of the NID driver understanding the possibility that the decoder could misinterpret the neural impulse and the NID driver then fails to take rectification steps within an appropriate time. The difficulty in separating the actions of the NID driver from those of the neural interface device creates problems in the application of each of these factors. These factors would act against the finding that the action of the neural interface device was an intervening act.

For these reasons, the court may decide that the NID driver moving through the Give Way sign, the mind sending neural impulses to the decoder, the decoder interpreting the command and instructing the neuroprosthetic leg to operate and any communication from the neuroprosthetic leg to the brain are part of a set of conditions necessary for the occurrence of the collision with the other vehicle and so factual causation is established. When considering how the causation difficulties might be resolved, legal practitioner L3 in the Delphi Method research said:

> Given the technology, I would have thought there might be data available to identify causation with some additional precision than contemplated above -- sort of like 'black box data' which could, for example, identify whether the instruction from the brain was turn left but the arm turned right, or not brake (pull instead of push). The availability of something like that would be very helpful in the determination of causation.

Such a mechanism could assist the court and once factual causation has been established, the court will need to consider the scope of the defendant's liability as the final step in determining the damage element of negligence.

2 *Scope of Liability*

Scope of liability rated 14th out of 23 in importance for members of the judiciary while legal practitioners rated it 13th out of 23 in importance and law academics rated it 21st out of 23 in

importance. The Civil Liability Legislation provides for this.[548] For example, the *CLAQ* s 11(1)(b) provides that 'it is appropriate for the scope of the liability of the person in breach to extend to the harm so caused (***scope of liability***)'.

Determination of the scope of the defendant's liability 'is not a question of fact or "common sense" but of normative judgment on which reasonable minds might differ.'[549] However, as discussed above, the blurring of the distinction between factual causation and scope of liability was not resolved by the Ipp Report.[550] Indeed, Stapleton argues that it is regrettable that the question of scope of liability was framed in causal terms and as a consequence:

> It might suggest that the fundamental notion of a "cause" may differ in different areas of the law. Another danger is that it may lead a judge merely to assert that the context of the relevant legal rule requires the connection between breach and result to possess a particular feature without explaining why this is so, a particularly serious state of affairs in the commercial context where typically both sides to a dispute are repeat players who require clear guidance from the courts so they can plan future conduct.[551]

This normative approach required by the legislation does not displace the common law methodology of the application of precedent and 'a policy choice once made is maintained unless confronted and overruled.'[552] Stapleton warns that scope of liability 'cannot be reduced to some formula' but it 'contains some internal structure'.[553]

> For example, we can say that a consequence will fall outside the appropriate scope of liability for negligence unless it at least: can plausibly be said to fall within the 'perimeter rule' of 'foreseeability of the type of harm';[554] is 'damage' relative to the normal expectancies of the

[548] *CLWACT* ss 45(1)(b), (4); *CLANSW* ss 5D(1)(b), 4; *CLAQ* ss 11(1)(b), (4); *CLAS* ss 34(1)(b), (4), *CLAT* ss 13(1)(b), (4); *WAVIC* ss 51(1)(b), (4); *CLAWA* ss 5C(1)(b), (4). There are no equivalent provisions in the Northern Territory.

[549] Stapleton, 'Reflections on Common Sense Causation in Australia', above n 507, 352.

[550] 109 (footnote 6); 117-8 (Recommendation 29).

[551] Stapleton, 'Reflections on Common Sense Causation in Australia', above n 507, 353.

[552] *Wallace v Kam* (2013) 250 CLR 375, 385 [22].

[553] Stapleton, 'Factual Causation', above n 496, 484.

[554] Derived from *Overseas Tankship (UK) Ltd v Morts Dock & Engineering Co* [1961] AC 388 ('*Wagon Mound (No 1) Case')* and *Hughes v Lord Advocate* [1963] AC 837.

> plaintiff absent torts;[555] is not a coincidental consequence;[556] and is the result of one of the risks that made the conduct careless.[557]

Applying this 'perimeter rule' in the context of the scenario above, the NID driver's liability for the damage to the other vehicle is appropriate as the damage is reasonably foreseeable, the damage would not have occurred absent the NIDs breach of the duty of care, it is not a coincidental consequence, that is, driving through a Give Way sign without ensuring the intersection was clear increases the chance of damaging another driver's car, and the resulting collision is one of the risks that made the conduct careless. 'On the conventional definition a consequence of a factor is only coincidental if, as a general matter, that type of factor does not increase the rate of occurrence of that type of result.'[558] As Stapleton explained:

> where a speeding bus is struck by lightning the speeding was a factual cause of the bus being struck but this consequence of the breach of duty was coincidental because, as a general matter, speeding does not increase the rate of occurrence of such lightning strikes.[559]

Policy and value judgments will also be considered when the court is determining the scope of liability of the NID driver. As discussed above,[560] there will be many policy or value judgments that will influence a decision in a negligence action. In relation to scope of liability, value judgments must be made to ensure that an absurd, unjust or unacceptable result that

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[555] Jane Stapleton, 'Cause-in-Fact and the Scope of Liability for Consequences' (2003) 119 *Law Quarterly Review* 388, 401, 412–17. *Travel Compensation Fund v Tambree* (2005) 224 CLR 627 runs counter to the usual judgment that if, but for the breach of an obligation of care, the plaintiff would have suffered an equivalent loss in a different transaction, it lies outside the appropriate scope of liability.

[556] Jane Stapleton, 'Occam's Razor Reveals an Orthodox Basis for *Chester v Afshar* (2006) *Law Quarterly Review* 426, 438ff.

[557] Jane Stapleton, 'The Risk Architecture of the *Restatement (Third) of* Torts', (2009) 44 *Wake Forest Law* Review 1309, 1324-5; Jane Stapleton, 'Factual Causation', above n 496, 484.

[558] Stapleton, 'Reflections on Common Sense Causation in Australia', above n 507, 355.

[559] Ibid 355.

[560] Under the heading '*3* Application of the Factors Determining Standard of Care'.

would 'prevent the law concluding that the negligence caused the harm'[561] does not occur. However, Stapleton warns:

> In my view, appeals to "common sense causation" or assertions about the "scope of the duty" not only obscure the task of identifying that it is this normative scope question that is in dispute but also hinder how clearly courts communicate their answers to it.[562]

To this extent, the NID driver's actions, regardless of whether the communication between the NID driver's brain and neural interface device can be scientifically determined, was the legally significant cause of the harm to the other vehicle. To assert otherwise would undermine the law that every driver has an established duty of care to other drivers to drive with such care and attention to avoid harming others. Whilst the facts of every negligence action involving a person with a neural interface device will be unique, the principles underlying the determination of scope of liability will apply to ensure that an absurd, unjust or unacceptable result that prevents the law concluding that the negligence caused the harm[563] will be avoided. For example, it is likely that the scope of liability in negligence will extend to cover many who engage in careless acts, such as the person in the Delphi Method stimulus who drops a box of books that causes harm to another person.[564]

3 *Liability of Neural Interface Device Manufacturer and the NID Driver*

A list of possible events that involved communication between the NID driver's mind and the NID driver's neuroprosthetic leg were outlined in the scenario above.[565] It was argued that it may have been any one of those events and that the event satisfied the 'but for' test of causation. Also raised in the scenario was the issue of attribution of liability between the NID driver and the manufacturer of the neuroprosthetic legs as this will be a very difficult task for the court because of the complexity of the neural interface device technology.

This technology was discussed in chapter 2. Briefly, the human mind sends a command in the form of neural impulses to the decoder that records and interprets the neural impulse

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[561] *Wallace v Kam* [2012] NSWCA 82, [12]-[13].
[562] Stapleton, 'Reflections on Common Sense Causation in Australia', above n 507, 360.
[563] *Wallace v Kam* [2012] NSWCA 82, 13.
[564] See Appendix 3.2 The Delphi Method Research Stimulus.
[565] See (a) The Scenario.

command and then sends instructions to the assistive device to operate as the neural impulse has commanded. The assistive device can send information back to the brain. In the NID driver scenario, the neural interface device includes an assistive device that is a neuroprosthetic leg. While the intended commands from the person's mind constitute one part of the communication, the interpretation of those commands, the instructions sent to the assistive device and the information sent from the assistive device back to the brain, constitute the other parts of the complex puzzle, not to mention any other factors external to these elements, such as the sound of a warning mechanism like a car horn.

In the context of the NID driver scenario, there might not have been a breach of the NID driver's duty of care but a combination of communication issues between the mind and the neural interface device. It must be established that 'but for' the negligent communication between mind and machine, the harm would not have occurred. It will need to be proven by the plaintiff what the person's brain intended to be done, what instruction the decoder interpreted, what instruction was sent to the assistive device, what information was sent by the assistive device to the decoder then the brain and how the brain responded. As discussed in chapter 2[566] and under the heading *1* Factual Causation above, current scientific expertise is unlikely to be able to determine definitive answers to these questions.

The facts of each case and attribution of liability between parties will differ but legislation provides the mechanism for determining such apportionment. In essence, the contribution recoverable is what is just and equitable, having regard to the extent of that party's responsibility for the damage.[567] This includes not only the defendant but attribution of liability for contributory negligence. It will be the conduct of each party in the circumstances that will enable the court to determine liability.

Dependant on the facts, many factors in relation to factual causation, as discussed above, will be very difficult, or impossible, to determine. Therefore, attribution of liability between the NID driver and the manufacturer of the neural interface device will also be difficult. There may be additional factors such as accreditation of the neural interface device discussed in

[566] Under the heading '*D* Limitations of Neural Interface Device Technology'.

[567] *CLWACT* ss 20, 21(2), (3), 102(1); *Law Reform (Miscellaneous Provisions) Act* 1965 (NSW) ss 5, 5(2), 9(1); *Law Reform (Miscellaneous Provisions) Act 1956* (NT) ss 12, 13, 16(1); *Law Reform Act 1995* (Qld) ss 6, 7, 10(1); *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 2001* (SA) ss 12, 6(5), (7), 7(1), (2); *Wrongs Act 1954* (Tas) ss 3, 3(2), 4(1); *WAVIC* ss 24AA, 24(2), 26(1); *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act* 1947 (WA) ss 7, 7(2), 4(1).

chapter 5 and compulsory third party insurance discussed in chapter 1 that might also play a role in enabling the court to be just and equitable when attributing liability.

E *Defences*

Defences were identified by the participants of the Delphi Method research as eighth out of 23 in importance of the legal issues that will arise. The importance of defences rated differently between the professional categories in the research. Law academics rated it as the third most important issue, members of the judiciary rated defences 11th most important and legal practitioners rated it 14th.

1 *Contributory Negligence*

It would be reasonable for the NID driver to plead contributory negligence should there be material facts in support of that defence. For example, if the other driver was not driving with due care and attention and could have otherwise avoided the accident enabling the NID driver to prove contributory negligence, the NID driver's liability will be reduced.[568]

2 *Volenti Non Fit Injuria*

The common law defence of *volenti non fit injuria* requires the plaintiff to have accepted total consequence for the defendant's neglect for the plaintiff's safety, in effect, the defendant owed the plaintiff no duty of care.[569] The Civil Liability Legislation has included this defence in circumstance where a person suffering harm is deemed to have been aware of an obvious risk unless they can prove otherwise.[570]

For example, *CLAQ* s 14 states:

> **14 Persons suffering harm presumed to be aware of obvious risks**
> (1) If, in an action for damages for breach of duty causing harm, a defence of voluntary assumption of risk is raised by the defendant and the risk is an obvious risk, the plaintiff

[568] Ibid.

[569] *Imbree v McNeilly* (2008) 236 CLR 510, 536 [81].

[570] *CLANSW* s 5G; *CLAQ* s 14; *CLAS* s 37; *CLAT* s 16; *WAVIC* s 54; *CLAWA* s 5N. There is no equivalent provision in Australian Capital Territory or the Northern Territory.

is taken to have been aware of the risk unless the plaintiff proves, on the balance of probabilities, that he or she was not aware of the risk.

Editor's note—

'Voluntary assumption of risk' is sometimes stated as 'volenti non fit injuria'.

(2) For this section, a person is aware of a risk if the person is aware of the type or kind of risk, even if the person is not aware of the precise nature, extent or manner of occurrence of the risk.

It might be argued that it is dangerous for the public to interact with a person who has a neural interface device and that anyone who does so should be made aware of the danger of such a device not operating as a biological limb. This would presume that, like a normal prosthetic limb, the neural interface device is easily identified as being different from the biological limb. In turn, it could be argued that the presumption of knowledge of obvious risks of engaging with a person who has a neural interface device would exist. Such a presumption of knowledge of obvious risks[571] currently exists in Civil Liability Legislation as outlined above. This defence is unlikely to arise where the person with the neural interface device is interacting with the public unless the shortcomings of neural interface devices become regarded as obvious risks, are known by the public and the person injured is aware that they are interacting with a person with a neural interface device.[572] The specific activity that is being engaged in is not important because it is the risk of engaging with the person with the neural interface device that will need to be obvious for the *volenti* defence to be sustained.

In the Delphi Method research,[573] participants ranked *volenti* 20th in importance out of 23. Similarly, the materialisation of an inherent risk absolves a person.

3 *Inherent Risk*

When considering what constitutes an inherent risk or danger at common law, McHugh J stated, 'The only risks or dangers that are inherent in activities are those that cannot be avoided by the exercise of reasonable care'.[574] Now, under Civil Liability Legislation, the NID

[571] See, for example, *CLAQ* s 14.

[572] Ibid.

[573] See III chapter 3 Legal Analysis Using the Delphi Method.

[574] *Vairy v Wyong Shire Council* (2005) 223 CLR 422, [50].

defendant will not be liable for the materialisation of an inherent risk.[575] For example, *CLANSW* s 5I states:

> **5I No liability for materialisation of inherent risk**
> (1) A person is not liable in negligence for harm suffered by another person as a result of the materialisation of an inherent risk.
> (2) An "**inherent risk**" is a risk of something occurring that cannot be avoided by the exercise of reasonable care and skill.
> (3) This section does not operate to exclude liability in connection with a duty to warn of a risk.

In *Nair-Smith v Perisher Blue Pty*,[576] Perisher Blue sought the application of the defence of no liability pursuant to *CLANSW* s 5I. Beech-Jones J considered whether or not the respondent's injuries were the result of the materialisation of an inherent risk involved in the act of boarding a chairlift at a ski resort:

> Perisher contended that the fact that 'the safety bar was down, and that it had to be rectified in 0.8 of a second ... [meant] that urgent remedial action, and the spectacle of that action being taken by the load lift attendant, was an inherent risk of the loading procedure in which [Dr Nair-Smith] was engaged' within the meaning of s 5I. However, the findings that I have made to this point are to the effect that the risk that was presented by the safety bar being down was one that could have been avoided by the exercise of reasonable care and skill on the part of the lift operator. I reject Perisher's defence under s 5I.[577]

The NSW Court of Appeal affirmed the decision, stating:

> In order for there to be no liability for the materialisation of an inherent risk it must be proven, inter alia, that the risk "cannot be avoided by the exercise of reasonable care and skill". The relevant risk in this case is that a skier may sustain physical injury as a result of his or her reaction to the manner in which a lift operator responds to a down bar situation. As stated at [137] above, this risk could have been avoided had Mr Lofberg observed the state of chair as it left the

[575] *CLANSW* s 5I; *CLAQ* s 16; *CLAS* 39; *WAVIC* s 55; *CLAWA* s 5P. There is no equivalent provision in Tasmania, the Australian Capital Territory and the Northern Territory.
[576] [2013] NSWSC 727.
[577] *Nair-Smith v Perisher Blue Pty* [2013] NSWSC 727, [173]

bullwheel. The relevant risk is therefore not of the character described in s 5I. We agree with the primary judge.[578]

In the context of the NID driver scenario, it could be argued that misinterpretation of neural impulse by the decoder cannot be avoided by the exercise of reasonable care and skill by the NID driver. For this reason, the legislative defence of inherent risk may well be available to a person with a neural interface device. However, the court could determine that the risk presented by the neural interface device could have been avoided by the exercise of reasonable care and skill on the part of the NID driver in seeking to apply the brakes at a time that would enable adequate response to neural misinterpretation to avoid the accident. Product accreditation may play role in determining an acceptable error rate, however, this might only reinforce the inherent risks that exist with these types of devices. Chapter 5 discusses product accreditation under standards set by the government authority, in Australia, the Therapeutic Goods Administration (TGA).[579]

F *Summary*

The above analysis reveals that the standard of care, determined by the application of Civil Liability Legislation, should be that of a reasonable person with the same, or similar, neural interface device in the same, or similar, circumstances. This variation of the standard of care might result in a lower standard of care than that of the standard of care of a person without a neural interface device. Factors supporting this include:

1. A neural interface device is not a biological limb;
2. Communication between the brain and the neural interface device is not as accurately interpreted by the device as the communication between the brain and the biological limb;[580]
3. The impulses from the device may alter the workings of the brain in ways identified, for example, when deep brain stimulation is used for treatment of Parkinson's Disease;[581] and

[578] Ibid [167] (Barrett JA; Gleeson JA; Tobias AJA).

[579] See analysis under the heading '*1* TGA Approval'.

[580] Ohnishi, Weir and Kuiken, above n 373, 43.

[581] Carter A, Bell E, Racine E and Hall W, 'Ethical Issues Raised by Proposals to Treat Addiction Using Deep Brain Stimulation' (2011) 4 *Neuroethics* 129, 134.

4. Policy considerations, such as the benefit to society for its citizens in need to be able to have these neural interface devices, justify the increased risk of harm to the public.

Alternatively, the analysis above also supports the argument that the standard of care should be higher than that of the person without a neural interface device if a person with a neural interface device is required to do one or more of the following:

1. Undergo a specified training program to facilitate competence in operating the neural interface device;
2. Undergo specific training to recognise and anticipate adverse outcomes;
3. Take necessary precautions to minimise adverse outcomes;
4. Acknowledge that the abilities of the neural interface device are an enhancement of human attributes; or
5. Obtain compulsory insurance against damage or injury caused to another's property or person, like the compulsory third party insurance required of motor vehicle owners. Delphi Method research participant P6 said:

> It would seem to me that any user of such a device would be well advised to take out insurance to cover the possibility of imperfect performance of the device, as such a precaution might well be considered to be the appropriate (and therefore 'reasonable') response to such potential incidents.

When applying the concept of revolutionary science[582] to this analysis, the tension that neural interface devices will have on the existing standard of care may give rise to a variation resulting in a different standard of care to be applied to a defendant with a neural interface device.

The risks apparent to the defendant, his or her capacity to meet those risks and the circumstances under which he or she must act will also be considered by the court. The precautions undertaken by the person to minimise the chance of injury to another will generally be expected, therefore, the standard of care to be applied is uncertain, However, consideration of a different standard of care for this new class of person on the application of the Civil Liability Legislation appears inevitable. As stated by Braidotti:

[582] See Kuhn, above n 2.

> At their most ambitious, efforts to compensate for damaged or destroyed sensory organs have come to involve the invention, manufacture and implantation of bionic counterparts for eyes and ears. These connect the conscious mind and the vibrant, colourful, noisy external world – with life changing consequences for recipients.
>
> Once the stuff of science fiction, the bionic enterprise of today is built on a realisation that has transformed human innovation during the past decade; that no single discipline in science, engineering or medicine is up to the task. Instead, each specialist field has mastered some of the components needed to solve an overall problem, whether related to vision, hearing or any other among a spectrum of healthcare challenges.[583]

The specialist field of law will also need to prepare for the incorporation of neural interface devices with the human body. The human brain will communicate with these neural interface devices through efferent and afferent communication[584] between the device and the brain.[585] This melding of mind and machine challenges the law in determining where civil liability for injury, damage or loss should lie.

Factual causation will be of critical importance in determining a negligence action against a person with a neural interface device but the court will be faced with the difficulty of acquiring knowledge and understanding of the specific roles the individual and the neural interface device played in causing the harm. This will impact on attribution of liability between the person with the neural interface device and the manufacture of the device. As a legal practitioner who participated in the Delphi Method research presented in chapter 3 said:

> The real issue will be breach, causation, foreseeability all of which will involve understanding the extent of the risk of imperfect translation and what should have been the reaction of the user and the person who enabled the user to use the device.

Neural interface devices and their incorporation into the human body is so radically different or unique from any other circumstance previously considered by the courts, that the law should recognise a different or unique application of the law of negligence. The analysis of the current law in this chapter has highlighted a possible variation of the objective standard

[583] Braidotti, above n 154, 10.

[584] Information flowing from both the brain to the device and from the device back to the brain, respectively.

[585] IEEE Engineering in Medicine and Biology Society, above n 124, 19.

of care applied to the reasonable person because this may better recognise this new class of person whose biological body part has been replaced with a neural interface device. Therefore, the standard of care should be that of a reasonable person with the same, or similar, neural interface device in the same, or similar, circumstances. Any challenges regarding neural interface devices that the court might experience, could be addressed in the way Justice McHugh recommended in *Perre v Apand Pty Ltd*, '[w]hile *stare decisis* is a sound policy because it promotes predictability of judicial decision and facilitates the giving of advice, it should not always trump the need for desirable change in the law'.[586] The anomalies revealed in this chapter's analysis will, over time, become fully congruent within the re-evaluation and adaptation of the law of negligence.[587]

[586] (1999) 198 CLR 180, 216 [92].

[587] See Kuhn, above n 2, 77-8.

V CHAPTER 5 MANUFACTURER LIABILITY

A *Introduction*

Chapter 4 analysed the law of negligence as applied to a defendant who has a neural interface device. It was stated that liability for harm could be attributed to the manufacture of the neural interface device, so the purpose of chapter 5 is to examine factors a court should consider when determining the extent to which a neural interface device manufacturer could be held liable for the harm suffered by the plaintiff. Technical analysis of neural interface devices in chapter 2[588] noted that the degree to which a neural interface device is incorporated into the human body varies considerably. A neuroprosthetic device might be strapped to the body in a similar way as a traditional prosthetic limb and is provided with commands from the brain through the recording and decoding of neural impulses to nerve bundles in what remains of the person's limb. Some devices currently available, like the cochlear implant, are inserted into an orifice of the human body, sending information to the brain via the adjacent nervous system. Neural interface devices, such as BrainGate, are surgically attached to, or implanted in, the human body interpreting neural impulses to instruct an artificial assistive device and relay information to the brain directly via the nervous system.[589]

If a person with a neural interface device is a defendant in a negligence action for recovery of compensation for property damage or personal injury, the varying degrees of interface of the device with the human body will be of importance. The operation of neural interface devices replicates that of a biological body part so, arguably, go beyond being simply a tool. These devices are so closely incorporated into the human body that the court may have difficulty determining causation, as analysed in chapter 4,[590] hence, liability for the injury or damage sustained. Under these circumstances, the law regarding manufacturer liability may play an important role.

[588] See analysis under the heading '*C* Neural Interface Device Technology'.

[589] BrainGate Co, above n 61.

[590] See analysis under the heading '*D* Causation'.

The importance of manufacturer liability was raised by participants in the Delphi Method research analysed in chapter 3. The Delphi Method research stimulus[591] eliminated malfunction of the neural interface device to ensure that product liability would not determine liability of the manufacturer. Part VA of the *Trade Practices Act 1974* (Cth) was inserted in 1992 establishing strict liability of manufacturers and importers for defective products.[592]

> The purpose of this Bill is to introduce into Australia a strict product liability regime based on the 1985 European Community Product Liability Directive by way of amendment of the Trade Practices Act 1974. It provides a regime of strict liability, whereby a person who is injured or suffers property damage as a result of a defective product has a right to compensation against the manufacturer without the need to prove negligence on the part of the manufacturer.[593]

The *Trade Practices Act 1974* (Cth) was amended to become Schedule 2 of the *Competition and Consumer Act 2010* (Cth), known as the *Australian Consumer Law* (*ACL*), so Part VA became Part 3-5 (sections 138-150) of the *ACL*.[594] Pursuant to the *ACL* if the neural interface device is acquired by a consumer[595] the manufacturer of a good with a safety defect is liable to compensate the consumer for loss, injury or damage suffered because of the safety defect.[596] In 2017, following an overview of the *ACL*, Consumer Affairs Australia and New Zealand proposed that there be an increase of the $40,000 threshold in the definition of 'consumer' to $100,000.[597] However, this financial threshold will not apply if the neural interface device is regarded as a good of a kind ordinarily acquired for personal, domestic or household use or consumption.[598] As a result, product liability was not examined in the analysis of manufacturer liability.

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[591] The information upon which the participants in the Delphi Method research responded. Appendix 3.2 provides a copy of the stimulus.

[592] *Trade Practices Amendment Act 1992* (Cth) s 4.

[593] Explanatory Memorandum, Trade Practices Amendment Bill (No. 2) 1991 (Cth) 2 [1].

[594] *Trade Practices Amendment (Australian Consumer Law) Act (No 1) 2010* (Cth).

[595] *Australian Consumer Law* s 3.

[596] Ibid s 138.

[597] Consumer Affairs Australia and New Zealand, *Australian Consumer Law Report*, Final Report (2017) 74-5.

[598] *Australian Consumer Law* s 3(1)(b).

This chapter considers the accreditation of neural interface devices, the labelling and information requirements and the legal challenges in determining liability of manufacturers in a negligence action if the neural interface device is considered to be more than just a tool.

B *Device Accreditation*

A number of the neural interface devices discussed in chapter 2,[599] such as BrainGate and the LUKE arm, have been developed in the United States where the Food and Drug Administration (FDA) has developed regulatory control of these devices. Class III medical devices include those products that create the gravest risk of injury from failure.[600] Eric Chan believes that the FDA should develop a new Class IV and IV-E accreditation for new 'neuroelectronic interface (also known as brain-computer interface)' devices.[601] Class IV would be used for treating disability and disease and Class IV-E for accrediting devices used for enhancement of human abilities.[602] In relation to therapeutic purposes and enhancement, Warwick argues that there is no 'clear and present line which divides the two'[603] so defining these two new categories will be difficult. Likewise, Karpin and Mykitiuk believe that the distinction is inadequate and unhelpful in guiding regulatory decision-making.[604]

1 *TGA Approval*

In Australia, the Therapeutic Goods Administration (TGA)[605] under the Commonwealth Department of Health is the governmental body responsible for accreditation of medical devices. The TGA regulates therapeutic goods by examining and evaluating evidence of

[599] Under the heading '*B* Neural Interface Systems and Devices'.

[600] US Department of Health and Human Services, Food and Drug Administration, *Learn if a Medical Device Has Been Cleared by FDA for Marketing* (29 December 2017) <https://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm>.

[601] Eric D Chan, 'The FDA and the Future of the Brain-Computer Interface: Adapting FDA Device Law to the Challenges of Human-Machine Enhancement' (2007) 25 *John Marshall Journal of Computer & Information Law* 117, 120.

[602] Ibid 156-7. The FDA has not introduced these suggested classes.

[603] Kevin Warwick, 'The Promise and Threat of Modern Cybernetics' (2007) 100(1) *Southern Medical Journal* 112, 112.

[604] Isabel Karpin and Roxanne Mykitiuk, 'Going Out on a Limb: Prosthetics, Normalcy and Disputing the Therapy/Enhancement Distinction' (2008) 16 *Medical Law Review* 413, 414.

[605] Australian Government Department of Health, *Therapeutic Goods Administration* <http://www.tga.gov.au/>.

their risks and benefits.[606] All regulatory decisions are made in accordance with the legislation as set out in the *Therapeutic Goods Act 1989* (Cth), *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).[607] Guidelines for accreditation are provided in the *Australian Regulatory Guidelines for Medical Devices* (ARGMD).[608] Part 1 of the ARGMD provides the classification of medical devices and outlines the differences between the Australian and European Union regulatory requirements. Medical devices are defined in the ARGMD to be those devices that are used for humans, have therapeutic benefits and generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body.[609] Neural interface devices are clearly included by this definition.

Within the TGA is the Office of Devices Authorisation (ODA) that is responsible for the pre-market regulation of medical devices and the Office of Product Review (OPR) that is responsible for post-market regulation of all therapeutic goods.[610] 'Medical devices range from bandages that would be put on a scratch to high-risk products such as pacemakers that are implanted in the body.'[611] The regulatory requirements vary, depending on what the device is and how it is to be used and this is done before a new medical device can be supplied to the market in Australia.[612] The classification levels for all medical devices, outlined in Table 5.1, are Class I, I – supplied sterile (Is), I – incorporating a measuring function (Im), IIa, IIb, III and active implantable medical devices (AIMD).[613] The risks associated with using medical devices can range from Class I where there is little or low potential risk to patients and users to Classes III/AIMD where there are significant potential risks.[614] Regulatory requirements increase from Class I through Classes Is, Im and IIa then Class IIb to the highest regulatory requirement for Classes III/AIMD.[615] The classification of medical devices is provided in Division 3.1 *Therapeutic Goods (Medical Devices)*

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606 Australian Government, Department of Health, *Product regulation according to risk*, 2 <http://www.tga.gov.au/file/5338/download>.

607 Australian Government, *Australian Regulatory Guidelines for Medical Devices* <http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>.

608 Australian Government, Department of Health, *Australian Regulatory Guidelines for Medical Devices* (May 2011) <http://www.tga.gov.au/sites/default/files/devices-argmd-01.pdf>.

609 Ibid 20.

610 Ibid.

611 Ibid.

612 Ibid.

613 Australian Government, *Product regulation according to risk*, above n 606, 3.

614 Ibid.

615 Australian Government, *Australian Regulatory Guidelines for Medical Devices*, above n 608, 21.

Regulations 2002 (Cth) and the classification rules are in Schedules 2 and 2A of those regulations.

Table 5.1 Classification of Medical Devices[616]

Classification(s)	Risk level	Examples
Class I	Low	Crutches Hospital beds
Class I - supplied sterile Class I - with a measuring function Class IIa	Low to Medium	Sterile surgical gloves Clinical thermometer measuring body temperature Dental drills or ultrasound machines
Class IIb	Medium to High	Surgical lasers Diagnostic X-ray
Class III	High	Prosthetic heart valves Absorbable surgical sutures
Active implantable medical devices (AIMD)	High	Pacemakers Artificial heart

Table 5.2 Classification Rules for Medical Devices[617]

If the device	then apply Classification Rule	Some examples are:
is invasive—that is, the device penetrates the body through a body orifice or is inserted into the body during surgery	3—classifications vary depending on intended purpose	surgical eye probe, ophthalmic knife, eye cannula, ear/nose/throat forceps, internal tympanostomy tube, tongue depressor, intraoral x-ray sensor, oral gag, oral suction unit, thermometer, vaginal speculum, urethral bougie, anoscope, proctoscope, colonoscope, stomal peg, tracheostomy tube.
is active—that is, the device depends on a source of energy for	4—classifications vary depending	diagnostic x-ray sources, MRI, air driven surgical drills and saws, patient monitors, electronic blood pressure measuring devices, diagnostic ultrasound, electronic

[616] Australian Government, *Product regulation according to risk*, above n 606, 3.

[617] Australian Government, *Australian Regulatory Guidelines for Medical Devices*, above n 608, 81-2.

If the device	then apply Classification Rule	Some examples are:
its operation and converts energy	on intended purpose	stethoscopes/thermometers, software, gas regulators, radioactive seeds, mechanical infusion systems.
contains a medicine	5.1—these devices are Class III	antibiotic bone cements, condoms with spermicide, heparin coated catheters, dressings incorporating an antimicrobial agent.
is for contraception or preventing sexually transmitted diseases	5.2—classifications vary depending on intended purpose	condoms, contraceptive diaphragms, contraceptive intrauterine devices (IUDs), surgically implanted contraceptive devices.
is for disinfecting, cleaning, rinsing or hydrating	5.3—classifications vary depending on intended purpose	contact lens solutions, comfort solutions, disinfectants for haemodialysis devices and endoscopes, sterilisers to sterilise medical devices, washer disinfectors.
not active and is intended to record x-ray diagnostic images	5.4—these devices are Class IIa	x-ray films, photostimulable phosphor plates.
contains non-viable animal tissues or derivatives	5.5—these devices are Class III	biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen, intra-ocular fluids, meniscul joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
is a blood bag	5.6—these devices are Class IIb	blood bags (including those containing or coated with an anticoagulant).

If the device	then apply Classification Rule	Some examples are:
is an active implantable medical device	5.7—these devices are Class AIMD	implantable pacemakers, defibrillators and nerve stimulators,
is an active device to control, monitor, or directly influence the performance of an active implantable medical device	5.7—these devices are Class III	clinician's programming devices for pacemakers, patient control devices for nerve stimulation devices.
for export only	5.8—these devices are Class I	
is a mammary implant	5.9—these devices are Class III	mammary implants.
is not covered by any of the previous rules in this table	2—classifications vary depending on intended purpose	devices intended to: collect body liquid where a return flow is unlikely immobilise body parts and/or to apply force or compression channel or store substances that will eventually be delivered into the body treat or modify substances that will be delivered into the body dress wounds.

Table 5.3 Conformity Assessment for Medical Devices[618]

Class of Medical Device	Most commonly used conformity assessment procedures	Declaration of Conformity legislative reference
Class I	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Schedule 3, Part 6, clause 6.6
Class I (measuring) and Class IIa (non-sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Assurance Procedures)	Schedule 3, Part 6, clause 6.6
Class I (sterile) and Class IIa (sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Schedule 3, Part 6, clause 6.6
Class IIb	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Schedule 3, Part 1 clause 1.8
Class III and Class AIMD	Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design)	Schedule 3, Part 1 clause 1.8
Systems or Procedure Packs	Part 7 (Procedures for Medical Devices Used for a Special Purpose)	Schedule 3, Part 7, clause 7.5

Classification rules 3, 4 and 5.7, identified in Table 5.2 above, are of particular importance to the accreditation of neural interface devices. In addition, conformity assessment for neural interface devices as Class III and Class AIMD medical devices is identified in Table 5.3 above.

[618] Ibid 113.

Schedule 2, Part 2 of the regulations provides rules for non-invasive medical device while Part 3 provides rules for invasive medical devices and implantable medical devices. Invasive medical devices are not surgically invasive but are be used to penetrate a body orifice of a patient.[619] If the neural interface device is designed to be placed on the body of a person and interpret neural impulses solely from the neural impulses sent to nerve bundles, then it will be a non-invasive medical device that will be classified as Class I unless it is falls within Parts 4 or 5.[620] It will fall within Part 4 if the device is to give or receive energy from the person, in which case it will be Class IIa or IIb.[621] It will fall within Part 5 if it is an active, implantable medical device, in which case it would be a Class AIMD.[622] An *active medical device for therapy* means:

> An active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap.[623]

Many of the neural interface devices that exist, or may one day exist, could be considered as an active medical device for therapy but may also be regarded as simply an active medical device that will be classified depending on whether or not it is surgically invasive or implantable.

If the neural interface device was to be inserted into a body orifice of a person, such as an ear, on a long-term basis, that being continuously for more than thirty days,[624] it would be a Class IIa or IIb.[625] If the neural interface device is a surgically invasive or an implantable medical device that is to be used on a long-term basis, it will be a Class IIa, IIb or III, depending on the intended location of the device.[626] For example, if the device is to be the total or partial replacement of the shoulder, hip or knee, it will be a Class III device.[627] A

[619] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Schedule 2, Part 3, Clause 3.1.
[620] Ibid Part 2, Clause 2.1.
[621] Ibid Part 4, Clause 4.2.
[622] Ibid Part 5, Clause 5.7.
[623] The Dictionary in the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).
[624] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Schedule 2, Part 1, Clause 1.1(c).
[625] Ibid Part 3, Clause 3.1(2)(c).
[626] Ibid Clause 3.4.
[627] Ibid Clause 3.4(4)(f).

cochlear implant is registered as a Class III device.[628] It is unlikely that a neural interface device would be regarded as an in vitro diagnostic (IVD) medical device because the purpose for which it is created is not for pathological testing.[629]

Therapeutic goods that have been approved by the TGA are listed on the Australian Register of Therapeutic Goods (ARTG)[630] and this is the 'central point of control for the legal supply of medical devices in Australia'.[631] For Class III medical devices, including devices such as total and partial hip, knee or shoulder joint implants, the TGA has stringent pre-market safety, quality and performance assessment. Class III medical devices are individually registered on the ARTG to enable them to be monitored on their safety, quality and performance.[632]

The *Therapeutic Goods Act 1989* (Cth)[633] provides that the regulations can specify the requirements for medical devices known as 'Essential Principles'. The devices must comply with six Essential Principles that are specified in Schedule 1, Part 1 *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) and nine other Essential Principles regarding design and construction, which apply to devices on a case-by-case analysis, that are provided in *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Schedule 1, Part 2:

General principles

1. Use of medical devices not to compromise health and safety.
2. Design and construction of medical devices to conform to safety principles.
3. Medical devices to be suitable for intended purpose.
4. Long-term safety.
5. Medical devices not to be adversely affected by transport or storage.
6. Benefits of medical devices to outweigh any side effects.

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[628] ARTG Entry 230668 MED-EL Implant Systems Australasia Pty Ltd - MAX Programming Interface - Cochlear implant assessment system.

[629] The Dictionary in the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) defines IVD medical device.

[630] Australian Government, Department of Health, *Australian Register of Therapeutic Goods* <http://www.tga.gov.au/australian-register-therapeutic-goods>.

[631] Australian Government, *Australian Regulatory Guidelines for Medical Devices*, above n 608, 22.

[632] Australian Government, Department of Health, *Reclassification of hip, knee and shoulder joint implants,* (7 July 2015) <http://www.tga.gov.au/medical-devices-reforms>.

[633] Section 63.

Principles about design and construction

1. Chemical, physical and biological properties.
2. Infection and microbial contamination.
3. Construction and environmental properties.
4. Medical devices with a measuring function.
5. Protection against radiation.
6. Medical devices connected to or equipped with an energy source.
7. Information to be provided with medical devices.
8. Clinical evidence.
9. Principles applying to IVD medical devices only.

Therapeutic Goods Act 1989 (Cth) ss 41CB, 41CC and 41CD provide for the creation and application of standards for medical devices. Paragraphs 41CC(2)(a)-(f) list the organisations from which standards may be specified.[634]

Assessment of Conformity with the Essential Principles for each of the classes is provided under the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Part 3, Division 3.2. The Conformity Assessment Procedures are set out in *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Schedule 3. This would include, for Class III devices, full quality assurance procedures, the type of examination procedures, the verification procedures, or the production quality assurance procedures.[635] Devices in each of the other classes will require a number of Conformity Assessment Procedures.[636]

The TGA monitors the devices that have been approved, collecting data from product sponsors, health professionals, patients and consumers.[637] The TGA periodically prepares reports on adverse events involving the devices and requires a yearly report from sponsors of devices that are Class III, Class AIMD and implantable Class IIb medical devices.[638]

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[634] *Therapeutic Goods Act 1989* (Cth) 41CC(2)(a)-(f):

(a) Standards Australia;
(b) the International Organisation for Standardization;
(c) the International Electrotechnical Commission;
(d) the European Committee for Standardization;
(e) the European Committee for Electrotechnical Standardization;
(f) any other organisation declared by the Minister by notice published in the *Gazette* or on the Department's website.

[635] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Part 3, Division 3.2, Regulation 3.6.

[636] Ibid Part 3, Division 3.2.

[637] Australian Government, *Product regulation according to risk*, above n 606, 5.

[638] Ibid.

In conclusion, the existing legislative framework for medical device accreditation can accommodate neural interface devices, despite the different forms they take. The extent to which emergency safety mechanisms and acceptable error margins are required will depend on the accreditation class allocated to the neural interface device. For example, the conformity assessment procedures for a neural interface device that is safety critical, and classified as a Class III or AIMD medical device, will be required to have full quality assurance procedures in compliance with the *Australian Regulatory Guidelines for Medical Devices*.[639] The extent of quality assurance procedures will be guided by the magnitude of harm that could occur if the system fails to operate as it should. In addition, data information storage in the neural processor or decoder could be similar to the 'black box' of an aircraft in order to protect the information if an accident occurs.[640]

2 *Product Information*

Conditions attached to the granting of TGA accreditation include the provision of information to the users of the therapeutic medical devices.[641] This will play a major role in establishing the neural interface device user's knowledge of the limitations of the device which in turn will impact on the reasonable steps the individual must take to avoid harming the person or property of another. The need to take reasonable steps to avoid harm to another was raised by participants in the Delphi Method research[642] and discussed in chapter 4 in relation to a negligence action.[643]

Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) Schedule 1, Part 2, Essential Principle 13 specifies the information that must be provided with medical devices. Some of the information will be of importance in determining manufacturer liability.

Regulations 13.3 and 13.4 are provided below in Figure 5.1.

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[639] Australian Government, Department of Health, above n 608, Schedule 3, Part 1 clause 1.8.

[640] Tony Bailey, 'Flight Data Recorders Built to Survive' (2006) *Avionics News* 38, 38; Office of Research and Engineering, *Flight Data Recorder Handbook for Aviation Accident Investigations* (National Transportation Safety Board, 2002).

[641] Schedule 1, Part 2, Essential Principle 13 *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).

[642] See Delphi Method research results in III chapter 3 Legal Analysis Using the Delphi Method.

[643] See analysis under the heading '*3* Application of the Factors Determining Standard of Care'.

Figure 5.1 Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)

13.3 Information to be provided with medical devices—particular requirements

The information mentioned in the following table must be provided with a medical device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4	Any particular handling or storage requirements applying to the device
5	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
6	Any special operating instructions for the use of the device
7	If applicable, an indication that the device is intended for a single use only
8	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
9	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only
10	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
11	The batch code, lot number or serial number of the device
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used
13	If the information provided with the device does not include the information mentioned in item 12—a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)
14	If applicable, the words 'for export only'

Note: In addition to the information mentioned in the above table, regulation 10.2 requires certain information to be provided with a medical device.

13.4 Instructions for use

(1) Instructions for the use of a medical device must be provided with the device.

(2) However, instructions for the use of a medical device need not be provided with the device, or may be abbreviated, if:

(a) the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and

(b) the device can be used safely for its intended purpose without instructions.

(3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used
3	Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)
4	Information about the intended performance of the device and any undesirable side effects caused by use of the device
5	Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device
6	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
7	Any particular handling or storage requirements applying to the device
8	If applicable, an indication that the device is intended for a single use only
9	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
10	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only
11	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
12	For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged; and (c) if appropriate, instructions for resterilisation of the device
13	For a medical device that is intended by the manufacturer to be sterilised before use—instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
14	Any special operating instructions for the use of the device
15	Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life
16	Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life

Item	Information to be provided
17	Information about any treatment or handling needed before the device can be used
18	For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose—sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination
19	For an implantable medical device—information about any risks associated with its implantation
20	For a reusable device: (a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and (b) an indication of the number of times the device may be safely reused
21	For a medical device that is intended by the manufacturer to emit radiation for medical purposes—details of the nature, type, intensity and distribution of the radiation emitted
22	Information about precautions that should be taken by a patient and the user if the performance of the device changes
23	Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions
24	Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device
25	Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device
25A	For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device
26	Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device
27	Information about the degree of accuracy claimed if the device has a measuring function
28	Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device
29	For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the ‘test principle’) on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only);

Item	Information to be provided
	(d) assay procedure including calculations and interpretation of results; (e) interfering substances and their effect on the performance of the assay;
	(f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision; (g) clinical performance characteristics, such as sensitivity and specificity; (h) reference intervals, if appropriate; (i) any precautions to be taken in relation to substances or materials that present a risk of infection

Regulation 13.4, Items 3, 15, 23 and 27 would be of particular importance in relation to express statement of the device limitations. This could also include the reasonable steps the person with the neural interface device must take to avoid harm or device malfunction. Items 14, 22 and 28 would be of importance in relation to the training a person with the device must undertake. These requirements under Regulations 13.3 and 13.4 would impact on liability of the manufacturer in a civil action in negligence as discussed in chapters 3 and 4.

C *Manufacturer Liability*

It could be argued that in the context of harm caused by a person with a neural interface device, the difficulty of ascertaining whether the cause was solely that of the individual or of the neural interface device is so complex that the inference of negligence (*res ipsa loquitur*) might apply, as discussed in chapter 4.[644] However, in determining attribution of liability of the person with the neural interface device and the manufacturer of the device, the particular acts or omissions of each of them will be considered in order for the court to make a decision regarding liability in negligence.

In considering liability, the courts will have difficulty establishing the degree to which the neural interface device can be attributed to the harm because of its integration with the person's body and mind.[645] As a result, traditional manufacturer liability will play a role. This was raised by the legal experts in the Delphi Method research conducted and is discussed

[644] See analysis under the heading '*4* Whether the Inference of Negligence (res ipsa loquitur) Applies'.
[645] See analysis in chapter 4 under the heading '*D* Causation'.

in chapter 3.[646] The technical sophistication of neural interface devices arguably means these devices will carry with them the increased possibility of failure to interpret neural impulses with 100% accuracy.[647] This shortcoming was identified and discussed in chapter 2.[648]

1 *Neural Interface Device When Regarded as a Tool*

Clausen considered brain-machine interface (BMI) as a 'highly sophisticated case of tool use',[649] while Søren Holm and Teck Chuan Voo considered a brain-machine interfaced prosthetic arm represented a tool that individuals used. Holm and Voo's theory makes it possible to distinguish between actions initiated by the individual as opposed to the technology, thereby enabling continued reliance on the existing legal frameworks.[650] The duty of care that normally exists would prevail so the responsibility for obtaining an operator's licence or insurance may rest on the person with the neural interface device.[651]

> Moreover, humans are often in control of dangerous and unpredictable tools such as cars and guns. Brain–machine interfaces represent a highly sophisticated case of tool use, but they are still just that. In the eyes of the law, responsibility should not be much harder to disentangle.[652]

However, neural interface device could be regarded as more than just a tool.

2 *Neural Interface Device Beyond Being a Tool*

It could be argued that neural interface devices, move beyond being simply a "tool" as a result of the integration with, and incorporation into, the human body and brain.[653] The melding of the mind and machine moves the use of the neural interface device beyond

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[646] See under the heading '*2* Round 1 Research Outcomes'.
[647] Ohnishi, Weir and Kuiken, above n 373, 43.
[648] See analysis under the heading '*D* Limitations of Neural Interface Device Technology'.
[649] Clausen, above n 4, 1080.
[650] Holm and Voo, above n 67, 62.
[651] Ibid.
[652] Clausen, above n 4, 1080.
[653] Holm and Voo, above n 67, 6.

traditional 'tool use'.[654] The scenario presented in chapter 4 involved an individual with neuroprosthetic legs.[655] In this instance the interaction between the neural interface device and the brain is so difficult to determine that this creates challenges for the courts in applying the existing law to determine liability in cases where harm occurs. Where an individual acts to the detriment of another person, there exists law to determine liability for misuse of the tool, such as a gun, where the manufacturer of the gun is not liable for the injury caused. Where there is melding of mind and machine with, for example, the integration of a neuroprosthetic arm or hand, efferent and afferent communication between the neural interface device and the human brain occurs. That is, neural impulses are sent from the brain, recorded and decoded by the neural interface device and the device sends information to the brain to assist the individual in the facilitation of the desired action. Under these circumstances, the neuroprosthetic arm or hand is arguably no longer simply a 'tool' when the courts are determining who should be held responsible for the damage caused to the property or person of another.

Holm and Voo considered manufacturer liability for such products and concluded that 'the "changed nature of human action" brought about by brain-machine interface technology does not quite change the very nature of responsibility for our actions'.[656] That is, despite the fact that the neural interface device is operating as a result of commands from the person's mind, this does not transfer all liability from the person to the neural interface device. Liability for wrongful acts will be determined in compliance with the legal principles relevant to the cause of action being pursued. For example, in a negligence action, factual causation will be assessed in the damage element of the action. Attribution of liability of the person with the neural interface device and the neural interface device manufacturer will then be decided by the court. Causation and liability implications are analysed in chapter 4.[657] However, the neural interface device will need to comply with the regulatory requirements discussed above.

Clausen believes that '[m]elding brain and machine makes the latter an integral part of the individual'.[658] Holm and Voo believe that legal issues arise if it becomes impossible to

[654] Ibid.

[655] See in the analysis of factual causation under the heading '(a) The Scenario'.

[656] Ibid.

[657] See analysis under the heading '*D* Causation'.

[658] Clausen, above n 4, 1080.

distinguish between the will of the person and the operation of the technology, where the natural neural system assimilates with the technology.[659] This was analysed in chapter 4.[660] If this occurs, Holm and Voo question whether the person will be held liable or just simply culpable to an appropriate standard and whether the person could plead the defence that it was 'the machine rather (or more) than I who did it'.[661]

Incidents that result in damage to a person or property in this situation will involve manufacturer liability. For example, an angry person responds subconsciously with a general thought of violence. The brain sends the impulse to the neural decoder that relays instructions to the neuroprosthetic arm to make violent contact with the victim's face. In the meantime, the angry person's knowledge of the inappropriate action has countered the desire to hit the other person, but it is too late for the neuroprosthetic limb to stop. The neural interface device has operated correctly. The dilemma for the medical personnel, insurers and lawyers is to determine where the responsibility should lie.

Determining manufacturer liability when the neural interface device has operated correctly will involve the court's examination of the manufacturer's obligations with respect to the provision of information, including warnings, as discussed above[662] together with the obligations that attach to the design, construction, manufacture and maintenance of the device. Evidence will be required to ascertain the commands that were sent from the brain to the signal processor and the instructions sent from the signal processor to the assistive device, as discussed in chapters 4.[663] However, every judicial decision will be dependent upon the particular circumstances of each dispute. Manufacturers of neural interface devices could benefit from research being undertaken in robotics and include operational steps that may impact on manufacturer liability.

For example, the development of robots to engage in military combat presents challenges in the robot's decision-making processes. Professor Ronald Arkin of the Georgia Institute of Technology is leading the research in this area to enable robots to self-determine when and

[659] Holm and Voo, above n 67, 6.
[660] See analysis under the heading '*D* Causation'.
[661] Ibid 2-3.
[662] See analysis in chapter 5 under the heading '*1* TGA Approval'.
[663] See analysis under the heading '*1* Factual Causation'.

who to attack and the appropriate weapon to use.[664] The actions of the robot would be guided by, what Arkin calls, an 'ethical governor' that checks a set of pre-programmed constraints based on the rules of engagement and the laws of war,[665] together with an 'ethical adapter' used to restrict the robot's weapon choices.[666] However, the 'responsibility governor' allows military personnel 'to override the conservatively programmed ethical governor if he or she decides the robot is too hesitant or is overreaching its authority.'[667]

If similar mechanisms were incorporated in the operation of neural interface devices, these would help to minimise unwanted neural interface operations. This research in robotics used in warfare provides avenues for neural interface device manufacturers to determine a degree of autonomous operation of neural interface devices by pre-programming prohibitions based on legal constraints, enabling the device to determine what action is appropriate and then finally enabling the individual to override these constraining mechanisms.[668] For example, the decoded neural impulse is commanding the neuroprosthetic arm to punch another person. The algorithms within the neural processor or decoder recognise this command to be in conflict with the law (ethical governor). The decoder then signals back to the brain that the command will not be fulfilled. The decoder chooses an appropriate gesture, holding up the hand to request behaviour to stop (ethical adapter). However, if the subsequent neural impulse sent back to the decoder is to punch regardless of the legal impediment (responsibility governor) effectively overriding the ethical governor, the decoder will send instructions to the neuroprosthetic arm to conduct the punch.

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[664] Carroll, above n 10, 80.

[665] International Committee of the Red Cross, *Geneva Conventions and Commentary* (27 December 2017) <https://www.icrc.org/en/war-and-law/treaties-customary-law/geneva-conventions>. The law or rules of war are incorporated in the Geneva Conventions which comprise of the following:

1. The First Geneva Convention "for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field";
2. The Second Geneva Convention "for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea";
3. The Third Geneva Convention "relative to the Treatment of Prisoners of War"; and
4. The Fourth Geneva Convention "relative to the Protection of Civilian Persons in Time of War".

[666] Carroll, above n 10, 84.

[667] Ibid. The method of machine governance incorporating similar steps that could be adapted for neural interface devices was discussed in Ron Arkin, *Governing Lethal Behavior: Embedding Ethics in a Hybrid Deliberative/Reactive Robot Architecture Part 3: Representational and Architectural Considerations* (Paper presented at the Proceedings of Technology in Wartime Conference, Palo Alto, CA, 26 January 2008) 8-9 <https://pdfs.semanticscholar.org/f4fa/da9d369957944b11f834a4e7e9cbef6af4d8.pdf?_ga=2.142305586.1063339984.1528353891-1535200378.1528353891>; Ronald Arkin, Patrick Ulam and Brittany Duncan, 'An Ethical Governor for Constraining Lethal Action in an Autonomous System (2009) *CSE Technical reports* 163, 163-5.

[668] Carroll, above n 10, 80.

The ability for such incorporation of an ethical governor, ethical adapter and responsibility governor could be considered in neural interface research and development. The incorporation of an ethical governor, ethical adapter and responsibility governor by the manufacturer of the neural interface devices could prevent a person inappropriately hitting another and this could assist in more accurately determining liability. That is, if the person overrode the ethical governor component of the neural interface device, arguably the manufacturer's liability will be reduced.

Other dimensions of neural interface device operation might play a role in the court's determination of manufacturer liability. For example, if the device can react spontaneously in a reflex action like parts of the natural human body can, or operate from the neural impulses without deliberate intent, the degree to which the manufacturer can be held liable goes beyond conscious mind control. When determining liability in these situations of unconscious, reflex reaction, or sane automatism[669] the courts will need to consider the ability for manufacturers to guard against or minimise the chance for the neural interface device to act in such a way. The neural interface device is responding solely to the neural impulses in the same way as a biological limb moves in a reflex reaction.

As discussed in chapter 2,[670] continuing research in order to better understand the functioning of the brain will assist in overcoming these challenges. For example, Professor Ross Cunnington, of the Queensland Brain Institute's Cunnington Laboratory, leads a group of neuroscientists who are researching how the brain processes sensory information including the 'fine circuitry of the basal ganglia, which are crucial for higher-order planning and control of voluntary movements.'[671]

Outcomes from research on how the brain functions will assist with the accuracy of neural decoding and the operation of the neural interface device. It is likely that the command from the brain will need to be much more certain than a subconscious response. In the scenario above involving the desire to punch another person, the biological arm would not have moved as a result of the unintentional emotional response to hit the other person. A

[669] 'Automatism that does not arise from a disease of the mind' Peter Butt and David Hamer (eds), *Concise Australian Legal Dictionary* (LexisNexis Butterworths, 4th edition, 2011), 521. 'Sane automatism includes actions committed while sleepwalking, during a fit, as a reflexive response to (e.g.) a bee sting' in Trischa Mann (ed), *Australian Law Dictionary* (Oxford University Press, 2010), 53-4.

[670] See analysis under the heading '*B* Neural Interface Systems and Devices'.

[671] Ross Cunnington, *Brain and Action* <https://qbi.uq.edu.au/cunningtongroup>.

conscious command was not sent from the brain, so the decoder would not have instructed the assistive device to operate. However, this would be dependent on the type of neural sensor operating. For example, if the sensor is an implant sitting on the motor cortex of the brain, a command to injure or attack the other person might have been sensed. This is highly unlikely because the brain will be controlling the actions of the body, ensuring deliberate acts are facilitated, and not simply an intuitive, emotional response. It will be imperative that neural interface device manufacturers ensure that the neural sensor only senses definitive neural commands of movement, not the background 'noise' of mere thoughts or desires. That is, action solely on conscious, intentional commands.

In the application of the current law of negligence, liability of the manufacturer of a neural interface device could be considered in the following way.

The duty of care owed by the manufacturer was established in *Donoghue v Stevenson*[672] and subsequently applied in *Grant v Australian Knitting Mills Ltd*[673]and *Suosaari v Steinhardt*[674]. The scope of the duty requires the manufacturer to take reasonable care in the manufacture of the product to prevent the product causing injury or loss to the consumer.[675]

The duty of a care of a manufacturer is an issue to be determined at common law. In the context of the NID driver scenario,[676] the manufacturer of the NID driver's neuroprosthetic legs (NID manufacturer) owes a duty of care to the NID driver. That duty is to take reasonable care in the manufacture of the neuroprosthetic legs to avoid reasonably foreseeable and real risk of injury.

As discussed above, determination of breach of the duty of care is no longer under common law but is now pursuant to the Civil Liability Legislation.[677] The standard of care of the NID manufacturer is that of reasonably competent manufacturer of neural interface devices and

[672] [1932] AC 562, 599.This finding was discussed in chapter 1 under the heading '*2* The Chosen Theory for Hypothesis Determination'.

[673] [1936] AC 85.

[674] [1989] 2 Qd R 477.

[675] *Dovuro Pty Ltd v Wilkins* (2003) 215 CLR 317, 328 [29] (McHugh J).

[676] See chapter 4 under the heading '(a) The Scenario'.

[677] See chapter 4 under the heading '*B* Statutory Modification of the Common Law'.

breach of the duty of care is determined by the application of the Civil Liability Legislation.[678] For example, the relevant provisions of the *Civil Liability Act 2003* (Qld) state:

> **9 General principles**
>
> (1) A person does not breach a duty to take precautions against a risk of harm unless—
>
> (a) the risk was foreseeable (that is, it is a risk of which the person knew or ought reasonably to have known); and
> (b) the risk was not insignificant; and
> (c) in the circumstances, a reasonable person in the position of the person would have taken the precautions.
>
> (2) In deciding whether a reasonable person would have taken precautions against a risk of harm, the court is to consider the following (among other relevant things)—
>
> (a) the probability that the harm would occur if care were not taken;
> (b) the likely seriousness of the harm;
> (c) the burden of taking precautions to avoid the risk of harm;
> (d) the social utility of the activity that creates the risk of harm.

Breach of that duty of care is a question of fact.[679] In applying *CLAQ* s 9(1)(a) when determining breach of duty of care,[680] the risk of injury to the NID driver, or the class to which the NID driver belongs (that is, consumers who require neuroprosthetic legs) is reasonably foreseeable if the NID manufacturer fails to ensure the neuroprosthetic legs operate correctly. This would be supported by the TGA guidelines for accreditation[681] that mandate the taking of precautions. For example, the conformity assessment procedures for the neuroprosthetic legs if they are classified as a Class III or AIMD medical device, will be required to have full quality assurance procedures in compliance with the *Australian Regulatory Guidelines for Medical Devices*.[682] It is highly probable that the accuracy of the neural processor, or decoder, is such that correct interpretation will result in correct

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[678] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B.

[679] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B; *Wyong Shire Council v Shirt* (1980) 146 CLR 40.

[680] *CLWACT* s 43(1)(a); *CLANSW* s 5B(1)(a); *CLAS* s 32(1)(a); *CLAT* s 11(1)(a); *WAVIC* s 48(1)(a); *CLAWA* s 5B(1)(a).

[681] See discussion above under the heading '*1* TGA Approval'.

[682] Australian Government, Department of Health, above n 608, Schedule 3, Part 1 clause 1.8.

instructions to the neuroprosthetic legs. Evidence of breach of statutory provisions or regulatory guidelines is not conclusive breach of the duty of care, but will be an influential factor to be considered by the court.[683] This might also include the NID manufacturer requiring the recipient of the neuroprosthetic legs to undertake training in order to develop operational proficiency and understand device limitations.

In applying *CLAQ* s 9(1)(b),[684] it could be argued that the risk of injury, that is, the NID driver having a motor vehicle accident, is not insignificant. When seen from the perspective of the NID manufacturer, the NID driver is clearly at risk. Failure of the neuroprosthetic legs to operate as commanded by the NID's neural impulses could result in a motor vehicle accident, a fact which a reasonable person in the position of the defendant should be aware.

In applying *CLAQ* ss 9(1)(c) and (2),[685] to determine whether there has been a breach of standard of care and subsequently the duty of care, the court is to consider the following (among other relevant things):

Under *CLAQ* s 9(2)(a),[686] the probability of injury occurring is arguably high. That is, if the decoder does not interpret the neural impulse correctly, it is highly probable that action or inaction will result in injury, identified in the NID driver scenario above.[687] As neuroprosthetic legs become available and used, probability based on statistics will assist in evaluation.

Under *CLAQ* s 9(2)(b),[688] seriousness of the harm must be considered. In the context of the NID driver scenario, the gravity of injury occurring as a result of an alleged breach is arguably serious because the result could be serious/permanent injury or death.[689]

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[683] *Tucker v McCann* [1948] VLR 222.

[684] *CLWACT* s 43(1)(b); *CLANSW* s 5B(1)(b); *CLAS* s 32(1)(b); *CLAT* s 11(1)(b); *WAVIC* s 48(1)(b); *CLAWA* s 5B(1)(b).

[685] *CLWACT* s 43(1)(c) and (2); *CLANSW* s 5B(1)(c) and (2); *CLAS* s 32(1)(c) and (2); *CLAT* s 11(1)(c) and (2); *WAVIC* s 48(1)(c) and (2); *CLAWA* s 5B(1)(c) and (2).

[686] *CLWACT* s 43(2)(a); *CLANSW* s 5B(2)(a); *CLAS* s 32(2)(a); *CLAT* s 11(2)(a); *WAVIC* s 48(2)(a); *CLAWA* s 5B(2)(a).

[687] See chapter 4 under the heading '(a) The Scenario'.

[688] *CLWACT* s 43(2)(b); *CLANSW* s 5B(2)(b); *CLAS* s 32(2)(b); *CLAT* s 11(2)(b); *WAVIC* s 48(2)(b); *CLAWA* s 5B(2)(b).

[689] *Road Traffic Authority of NSW v Dederer* (2007) 324 CLR 330, 340 [27].

Under *CLAQ* s 9(2)(c),[690] the practicability of, or burden of taking precautions must be considered. It would be relatively easy, not overly inconvenient and inexpensive (in comparison to the risk of injury) to carefully check the neuroprosthetic legs, follow the TGA guidelines and simply stop the devices that are not functioning correctly from reaching the market.[691] Another precaution could be the inclusion of a physical override mechanism to enable the NID driver to instruct the neuroprosthetic legs using hand operated controls rather than neural impulse. The court will consider expense, convenience and similar factors to determine if this, or other steps, are reasonable.[692] Other factors the court may consider include the following.

As neural interface devices develop, customary standards, such as neural interface device industry guidelines, from organisations like the Institute of Electrical and Electronics Engineers,[693] might eventuate. These industry guidelines may require specific tasks to be undertaken in the manufacture of neural interface devices. Compliance with these guidelines will be a factor the court will consider, however, non-compliance will be regarded as evidence of breach of the duty of care but will not be conclusive.[694]

The NID manufacturer should also anticipate the negligent conduct (or inadvertence) of the NID driver.[695] For example, there is a real possibility that the NID driver will not command the neuroprosthetic leg to apply pressure to the car brakes within time for the device to accomplish the command before colliding with the other vehicle. There may be no reasonable steps the NID manufacturer can take to guard against the NID driver's conduct. However, considering these types of negligent conduct or inadvertence and taking reasonable steps to counter such conduct will be a factor the court will consider in determining whether the NID manufacturer has breached the duty of care.

[690] *CLWACT* s 43(2)(c); *CLANSW* s 5B(2)(c); *CLAS* s 32(2)(c); *CLAT* s 11(2)(c); *WAVIC* s 48(2)(c); *CLAWA* s 5B(2)(c).

[691] *Road Traffic Authority of NSW v Dederer* (2007) 324 CLR 330, 407 [275].

[692] *Romeo v Conservation Commission (NT)* (1998) 192 CLR 431, 446-7 [24]-[25] (Brennan CJ); 454-6 [50]-[56] (Toohey and Gummow JJ); 480-1 [128]-[129] (Kirby J).

[693] Institute of Electrical and Electronics Engineers, Inc (IEEE), (2019) https://www.ieee.org/.

[694] *Tucker v McCann* [1948] VLR 222.

[695] *Roche v Kigetzis* (2015) 72 MVR 67; 76 [31]; [2015] VSCA 207, [31].

Finally, under *CLAQ* s 9(2)(d),[696] social utility of the NID manufacturer's conduct requires a comparison between the threat of injury to the NID driver versus some overall benefit to the community. It could be argued that the social utility of the neuroprosthetic legs which create the risk of harm serves a useful social purpose for a considerable number of people.[697]

Undertaking this application of the Civil Liability Legislation to the facts of a dispute will provide the court with the ability to decide whether or not, on the balance, the NID manufacturer breached the duty of care owed to the NID driver. This decision will impact on the liability of the NID manufacturer with respect to the damage caused to the car that was hit by the car being driven by the NID driver. However, as discussed above, factual causation may still present a problem as a result of the neuroprosthetic legs being so integrated with the human being.[698]

D *Conclusion*

Attribution of liability when the neural interface device operates correctly will be difficult to determine due to the complex interaction between the brain and the neural interface device. Aspects of operation including neural impulse decoding will play a role. In chapter 4[699] it was shown that accurate determination of what the neural impulse command actually was, will create difficulty for the court to assess liability. Chapter 5 examined three factors a court would consider when determining the extent of liability of a neural interface device manufacturer, for the harm suffered by the plaintiff. These factors were neural interface device accreditation, information provided by manufacturers to the recipients of neural interface devices and whether the device could be regarded as more than a tool.[700]

Requirements under therapeutic goods legislation[701] will be applied to determine accreditation of neural interface devices. In relation to functionality of the neural interface

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[696] *CLWACT* s 43(2)(d); *CLANSW* s 5B(2)(d); *CLAS* s 32(2)(d); *CLAT* s 11(2)(d); *WAVIC* s 48(2)(d); *CLAWA* s 5B(2)(d).

[697] *Harris v Bulldogs Rugby League Club Ltd* (2006) Australian Tort Reports ¶81-838, [60].

[698] See chapter 4 under the heading, '*1* Factual Causation'.

[699] See analysis under the heading '*1* Factual Causation'.

[700] See analysis above under the headings '*1* TGA Approval', '*2* Product Information' and '*2* Neural Interface Device Beyond Being a Tool', respectively.

[701] *Therapeutic Goods Act 1989* (Cth) and *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). Guidelines for accreditation are provided in the *Australian Regulatory Guidelines for Medical Devices* (ARGMD).

device, manufacturers will need to take reasonable steps to minimise unwanted actions that might contribute to the harm to another. Those steps could include mechanisms such as the ceasing of functionality if the neural impulse cannot be decoded with sufficient clarity, communication from the decoder to the brain for confirmation of command by the brain and mechanisms that incorporate an ethical governor, ethical adapter and responsibility governor.

While the melding of mind and machine moves the use of an active implantable medical device beyond traditional ‘tool use’, device accreditation is well placed to meet the demands of civil litigation. The degree to which manufacturers of neural interface devices will be held liable for damage to property or person as a result of the interaction of the device with the recipient will depend on the facts of each matter. The accreditation process will undoubtedly reduce the chance of holding the manufacturer liable, however, the more sophisticated devices that will interpret neural impulses directly from the brain will test the limits of the law in determining attribution of liability.

When applying revolutionary science, there is no crisis created by neural interface devices in the application of the law regarding manufacturer liability. The current law will apply without difficulty in both the regulation of neural interface devices and the imposition of obligations on manufacturers. Working together to facilitate movement, the brain and neural interface device will become as interrelated as the brain and a biological part of the human being. The acceptable error rate of the device might help shield the device manufacturer from liability but the court’s determination of the role the device played in causing the damage may be otherwise.

Having analysed the framework of neural interface devices in chapter 2, gathered insight from legal experts using Delphi Method research in chapter 3 and analysed both negligence and attribution of liability between the recipient of a neural interface device and the manufacturer in chapters 4 and 5, recommendations are made in chapter 6 that will assist with the re-evaluation and adaptation of the current law when resolving a negligence action.

VI CHAPTER 6 RECOMMENDATIONS AND CONCLUSION

A *Terms of Reference*

The earlier chapters of this thesis explored the impact that neural interface devices will have on the current law as they become more integrated into the human body. The research hypothesis analysed was that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve the subsequent civil action.

B *List of Recommendations*

These recommendations are based on analysis in previous chapters.

Negligence

Recommendation 1

In the application of the Civil Liability Legislation, the fact that the defendant has a neural interface device must be considered when determining the standard of care that should be applied.[702]

Recommendation 2

The operation by a person of a neural interface device is not to be regarded in the same way as the operation of a car or any other device that is independent of direct neural impulse from the individual.

Recommendation 3

Information contained within the neural interface device in relation to neural impulse recording and interpretation, together with the instructions that were sent to the assistive

[702] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAT* s 11; *CLAS* s 32; *WAVIC* s 48; *CLAWA* s 5B. There is no equivalent provision in the Northern Territory.

device and communication back to the brain, be retained for a set minimum period of time and is required to be disclosed to all parties during legal proceedings.[703]

Recommendation 4

Discussion of the public policy issues, including those in chapter 4,[704] should be undertaken by the governments, members of the judiciary and legal practitioners to assist in development of the law surrounding neural interface devices.[705]

Manufacturer Liability

Recommendation 5

The TGA's neural interface device accreditation process should ensure that the error rate of neural impulse decoding by the device is not substantially different from normal motor errors of the corresponding biological part.[706]

Recommendation 6

The conditions and assessment of conformity of neural interface devices must comply with the Australian Essential Principles.[707] .

Recommendation 7

The TGA requires manufacturers to provide product information for consumers, including the activities that should not be engaged in by the recipient of the device, in plain English.

[703] This would be best achieved as obligations under the rules of the court. This will be important in assisting with determination of causation, as discussed in chapter 4.

[704] Including indeterminate liability and coherence of the law. See chapter 4 analysis under the heading '(b) Policy Considerations'.

[705] This will assist in determining an appropriate balance between public benefit of neural interface devices and public risk.

[706] This will assist in determining an appropriate balance between public benefit of neural interface devices and public risk. See discussion in chapter 4 under the heading '(b) Policy Considerations'.

[707] The analysis of manufacturer liability in chapter 5 determined that neural interface devices must comply with six Essential Principles and nine other Essential Principles regarding design and construction, which apply to devices on a case-by-case analysis, all of which are specified in Schedule 1, Part 1 and Part 2 *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth), respectively.

Recommendation 8

Manufacturers incorporate in neural interface devices governance processes, such as an ethical governor,[708] ethical adapter and responsibility governor[709] to prevent misuse or inappropriate use of the devices.

C *Introduction*

Research for the thesis centred on the research hypothesis, when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action. It was important to engage with legal experts who identified the most significant legal issues associated with neural interface devices.

Chapter 1 provided an overview of this research area and the methodology that was employed to determine the research hypothesis. The significance of the research emphasised the original and substantial contribution to knowledge that this thesis provides as neural interface devices are still being developed and a civil action against a person with a neural interface device has yet to come before the courts.

Many issues were identified, however, the analysis of every issue was beyond the scope of this thesis. It was in these circumstances that the collection of data from legal experts was utilised by adopting the Delphi Method research methodology. The Delphi Method research methodology undertaken was outlined in chapter 1[710] and the following is a summary of the steps:

1. Development of the Research Question.
2. Designing the Research – The Delphi Method was used to collect the judgments and opinions of legal experts in the judiciary, legal profession and academia.

[708] Arkin, Ulam and Duncan, above n 667, 163-5.

[709] Carroll, above n 10, 80. The method of machine governance incorporating similar steps that could be adapted for neural interface devices was discussed in chapter 5 under the heading '*2* Neural Interface Device Beyond Being a Tool'; Arkin, above n 667, 8.

[710] The methodology was based on the Delphi methodology as used and reported in Skulmoski and Hartman, above n 51, 3-5. See chapter 1 under the heading '(b) The Delphi Method Research'.

3. Research Sample – The selection of research participants.[711]
4. The Stimulus – The stimulus was developed and tightly defined to provide the information to participants.[712]
5. Delphi Preliminary Studies –
    a. *Pre-test of the Stimulus*.
    b. *Pilot of online Research Instrument*.
6. Release Round 1 Research Instrument and Analyse Responses.
7. Development of Round 2 Research Instrument.
8. Release Round 2 Research Instrument and Analyse Responses.
9. Document Research Results.

The results of the Delphi Method research determined the structure of the chapters that followed. This was the analysis of the predominate legal issues identified by the participants in the Delphi Method research, namely negligence and manufacturer liability, which were conducted in chapters 4 and 5, respectively.

However, before undertaking the Delphi Method research, an understanding of the technical aspects of neural interface devices was required. Chapter 2 provided a brief overview of the technical framework upon which neural interface systems are being developed. This included a simplified version of the way in which the human brain communicates with the human body. The recording and interpretation of neural impulses by the neural processor within the neural interface system was outlined including the interface with the assistive device.[713] The device might include a computer, robot, robotic arm or artificial body part that is either placed on the outside of the human body or is incorporated within the body. While interfacing with an external computer or robot is advanced technology, the focus of the thesis was on neural interface devices that are integrated into the human body to the extent that they no longer exist as a separate and independent device but become an integral part of the human being. It is upon this basis that existing law regarding tool use cannot be adequately or appropriately applied without re-evaluation or adaptation.

[711] Ziglio, above n 326, 14. Ziglio acknowledges on this page that 'the definition of "experts" varies according to the context and field of interest in which the Delphi Method is going to be applied. Being and expert entails the acquisition of experience, special skill in or knowledge of a particular subject.'

[712] The stimulus was information provided to participants to ensure the legal experts would understand the research questions sufficiently to accurately address the issues.

[713] See chapter 2 under the heading '*A* Introduction' regarding the explanation that neural interface devices are synonymous with neural interface systems where neural activity is sensed to provide command signals to computers, machines and devices.

Chapter 2 made it clear that our understanding of how the human brain functions is incomplete and the technology that records and interprets neural impulse is far from perfect. Neural interfacing is not a perfect science and so the neural interface systems that provide the ability for people who have physiological and neurological injuries or developmental problems to interact in the world with greater freedom of movement, have their shortcomings. Accordingly, should a civil matter come before the court, experts will be required to provide the court with an understanding of the operation of the neural interface system and the limitations that must be considered. The predominant civil action likely to be brought against a person with a neural interface device is negligence and this was identified by legal experts in the Delphi Method research. The Delphi Method research outcomes were provided and examined in chapter 3.

Chapter 3 discussed the Delphi Method research undertaken and examined the insight of the Australian legal experts who participated in the research. Those experts identified the potential civil legal issues with neural interface devices and stated how the current law will apply to resolve those issues. Within negligence, the experts identified breach of duty of care (incorporating standard of care) and causation as major issues the current law will have difficulty applying to a defendant with a neural interface device. Manufacturer liability was also raised by the experts as a substantial legal issue. It was on the basis of this research that chapters 4 and 5 provided an analysis of negligence and manufacturer liability, respectively. The significance of using the Delphi Method is based on its ability to more accurately predict, examine and discuss legal issues. As there is yet to be a negligence action involving a person with a neural interface device, prediction of the different legal issues is much better achieved by enabling legal experts to collaborate.

Of particular interest was the assertion made by a number of experts that the common law is resilient enough to deal with the complexities that will arise with neural interface devices and that legislation should be avoided.[714] However, many of the experts considered that the current law will need to change. The tension between the common law and legislation was

[714] For example, Participant P6 stated:

> 'I would suggest that the complexities of these questions are such that they would be best left to the common law to resolve, and that interested parties should be very cautious about seeking legislation, as this will "freeze" the flexible development of appropriate laws.'

discussed in chapter 1[715] with the conclusion that to some degree there will be trial and error, as is often the case in terms of the development of new technology. The case law will evolve. It is highly likely that with this new technology, Federal and State governments will pursue a light touch regulatory approach to avoid interfering with the application of the current Civil Liability Legislation by the court. Many of the experts expressed the view that existing consumer protection legislation and Civil Liability Legislation was already able to be applied to a civil dispute in which a person with a neural interface device is involved.

Chapter 4 analysed negligence law and its application where the defendant has a neural interface device. While the defendant owes a duty of care to take reasonable care or to exercise reasonable skill identical to that of a fully able person, difficulty arises in determining the appropriate standard of care to be applied. Chapter 4 raised and analysed the many factors that the court should consider in determining breach of the duty of care, however, it was argued that for a person with a neural interface device the standard of care may be different from that of person without a neural interface device. The analysis in chapter 4 highlighted the possibility that the court may determine that individuals with neural interface devices form a new class of individual upon which a different standard of care should be applied. That standard of care, as determined by the application of Civil Liability Legislation,[716] would be the objective assessment of the actions of a reasonable person of ordinary prudence with the same or similar neural interface device in the same or similar circumstances. It is highly probable that the courts will need to address this in the near future.

Chapter 4 highlighted that factual causation will be of critical importance in determining a negligence action against a person with a neural interface device.[717] The specific role the individual and the neural interface device played in allegedly causing the harm will need to be determined and this will impact on attribution of liability between the person with the

[715] See discussion under the heading 'E Application of this Thesis'.

[716] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B. There is no equivalent provision in the Northern Territory.

[717] See chapter 4 under the heading '*1* Factual Causation'.

neural interface device and the manufacture of the device. In the Delphi Method research, legal practitioner L2 stated:

> The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation.

Participant P7 believed ‘The questions of causation are likely to be difficult.’

Legal practitioner L3 said:

> The real issue will be breach, causation, foreseeability all of which will involve understanding the extent of the risk of imperfect translation and what should have been the reaction of the user and the person who enabled the user to use the device.
>
> Given the technology, I would have thought there might be data available to identify causation with some additional precision than contemplated above -- sort of like 'black box data' which could, for example, identify whether the instruction from the brain was turn left but the arm turned right, or not brake (pull instead of push). The availability of something like that would be very helpful in the determination of causation.

Law Academic A2 said:

> It does not seem to me that there is anything particularly special about this context for the application of duty of care and causation principles though there will clearly be factual challenges in the latter.

While liability in negligence may fall upon the person with a neural interface device, liability might also be attributed to the manufacturer of the neural interface device.

Chapter 5 analysed liability of the manufacturer of neural interface devices. This included the need for device accreditation in Australia by the TGA or similar organisations in countries where the devices are manufactured or sold. As the neural interface devices cannot interpret neural impulses as accurately as the biological body part and the assistive device is not identical to the human body part, an acceptable margin of error should be incorporated into

the accreditation process.[718] Just how imperfect the neural interface device can be will provide the courts with constraints on the application of the objective standard of care. That margin of error required by the TGA may be extremely low for neuroprosthetic limbs if they are regarded as safety critical devices. Manufacturer liability where the neural interface device does not operate correctly presents less of a problem for the law.[719] The court will have difficulty determining liability between the individual and the neural interface device manufacturer where the device is operating correctly and a negligence claim is brought against the person with a neural interface device and the manufacturer.

Of particular concern to both an individual and the manufacturer of a neural interface device involved in a civil action is the communication that occurred between the brain and the neural processor. The recording of neural impulse and its interpretation will be contained within the neural processor and, like a black box in an aircraft,[720] this can provide courts with data upon which an understanding of the actions of the individual can occur. However, chapter 2 provided technical analysis that confirms that the recording and interpretation of neural impulse by the neural processor is not perfect.[721] Therefore, the admissibility of such evidence will need to be assessed. While evidentiary issues are beyond the scope of this thesis, a brief discussion of neuroscientific evidence is below[722] because parties to an action in negligence will seek to rely on neuroscientific evidence.

Recommendations that flow from the analysis conducted in this thesis are provided under the following broad headings of negligence and manufacturer liability. Determination of the thesis hypothesis is then considered. Just as chapter 1 identified other areas of inquiry regarding neural interface devices that are beyond the scope of this thesis, chapter 6 concludes with a brief discussion of further research opportunities that provide insight for those working on the application of the law to neural interface devices. These are neuroethics, neurolaw and neuroscientific evidence. The purpose of concluding in this way is to highlight the impact neural interface devices will have, recognising that this thesis seeks to contribute to the knowledge of this developing field of inquiry.

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[718] See chapter 5 under the heading '*1* TGA Approval'.

[719] See chapter 5 under the heading '*A* Introduction' regarding consumer protection against safety defects.

[720] Bailey, above n 640.

[721] See analysis under the heading '*C* Neural Interface Device Technology'.

[722] See discussion under the heading '*G* Further Research Opportunities'.

In summary, chapters 3, 4 and 5 provided identification and analysis of the legal issues that are anticipated to arise with respect to neural interface devices. Chapter 3 provided the outcomes of the Delphi Method research undertaken where legal experts identified the legal issues and considered how the law would address these issues. The predominant civil liability issue identified and discussed by participants in the Delphi Method research was negligence and chapter 4 provided analysis of negligence in the context of neural interface devices. Chapter 5 analysed manufacturer liability that was also identified as a major legal issue that arises with neural interface devices. The principal recommendations that flow from the analysis conducted in chapters 3 through 5 are as follows.

D *Negligence*

The melding of the human mind and a neural interface device makes the latter an integral part of the individual so legal issues will arise if it becomes impossible to distinguish between the will of the person and the operation of the technology, where the natural neural system assimilates with the technology.[723] Analysis of negligence in chapter 4 identified challenges in the application of the current law. The standard of care that would be applied to the defendant with a neural interface device through application of Civil Liability Legislation could result in a different standard of care from that of person without a neural interface device. This would be an objective test through the application of Civil Liability Legislation in respect of a person with a neural interface device, being that of a reasonable person with the same, or similar, neural interface device in the same, or similar, circumstances. The court will be faced with the difficulty of acquiring knowledge and understanding of the specific roles the individual and the neural interface device played in the circumstances where harm to another person or another person's property occurred. The difficulty in separating the actions of the person from those of the neural interface device creates problems in determining factual causation.[724] This will impact on attribution of liability between the person with the neural interface device and the manufacture of the device.

[723] Clausen, above n 4, 1080.

[724] See chapter 4 under the heading '*1* Factual Causation'.

Recommendation 1

In the application of the Civil Liability Legislation, the fact that the defendant has a neural interface device must be considered when determining the standard of care that should be applied.[725]

It is the ability of the person to act in unison with the neural interface device that enables action, not the person's physical control over a tool. The neural interface device is an integral part of the human body.

Recommendation 2

The operation by a person of a neural interface device is not to be regarded in the same way as the operation of a car or any other device that is independent of direct neural impulse from the individual.

Recommendation 3

Information contained within the neural interface device in relation to neural impulse recording and interpretation, together with the instructions that were sent to the assistive device and communication back to the brain, be retained for a set minimum period of time and is required to be disclosed to all parties during legal proceedings.[726]

Recommendation 4

Discussion of the public policy issues, including those in chapter 4,[727] should be undertaken by the governments, members of the judiciary and legal practitioners to assist in development of the law surrounding neural interface devices.[728]

[725] *CLWACT* s 43; *CLANSW* s 5B; *CLAQ* s 9; *CLAS* s 32; *CLAT* s 11; *WAVIC* s 48; *CLAWA* s 5B. There is no equivalent provision in the Northern Territory.

[726] This would be best achieved as obligations under the rules of the court. This will be important in assisting with determination of causation, as discussed in chapter 4.

[727] Including indeterminate liability and coherence of the law. See analysis in chapter 4 under the heading '(b) Policy Considerations'.

[728] This will assist in determining an appropriate balance between public benefit of neural interface devices and public risk.

E *Manufacturer Liability*

Chapter 5 provided an analysis of manufacturer liability and device accreditation, recognising that the melding of mind and machine moves the use of an active implantable medical device beyond traditional 'tool use'. Determination of a civil action may involve not only questions of fact but questions of law in relation to manufacturer liability.[729] The error rate of decoding of the neural impulse by the decoder will play a role in determining liability for harm to the property or person of another. An acceptable error rate might be higher than that of the corresponding biological part, but it will be important to accurately quantify the acceptable error rate as this will be a critical factor in a civil action. This will also assist in defending allegations of manufacturer liability. The court's determination of the role the device played in causing the damage will be based on the combination of many factors, as examined in chapter 4.[730]

Product accreditation by the TGA, as examined in chapter 5,[731] requires an understanding of this integration of mind and machine to appreciate the interaction between the device and the brain of the individual. Manufacturers should be required to provide product and operational information about the neural interface device[732] and neural interface devices will be required to conform with the Essential Principles in the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).[733] In chapter 5,[734] the use of an 'ethical governor' (set of pre-programmed constraints), 'ethical adapter' (programmed choices) and 'responsibility governor' (human override) from the research undertaken by Ronald Arkin was discussed and considered in relation to neural interface devices. These mechanisms will assist in preventing undesirable or unintended neural interface device movement.

[729] See also analysis in chapter 4 under the heading '*D* Causation'.
[730] See analysis under the heading '*1* Factual Causation'.
[731] See analysis under the heading '*1* TGA Approval'.
[732] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) Schedule 1, Part 2, Essential Principle 13.
[733] Sch 1, Pts 1 and 2.
[734] See analysis under the heading '*2* Neural Interface Device Beyond Being a Tool'.

Recommendation 5

The TGA's neural interface device accreditation process should ensure that the error rate of neural impulse decoding by the device is not substantially different from normal motor errors of the corresponding biological part.[735]

Recommendation 6

The conditions and assessment of conformity of neural interface devices must comply with the Australian Essential Principles.[736]

Recommendation 7

The TGA requires manufacturers to provide product information for consumers, including the activities that should not be engaged in by the recipient of the device, in plain English.

Recommendation 8

Manufacturers incorporate in neural interface devices governance processes, such as ethical governor,[737] ethical adapter and responsibility governor[738] to prevent misuse or inappropriate use of the devices.[739]

F *Determination of Thesis Hypothesis*

Determination of the thesis hypothesis, tested by the research questions assessed throughout the thesis, was considered using the concept of revolutionary science developed by Thomas Samuel Kuhn, as discussed in chapter 1.[740] Analogous with science, the courts

[735] This will assist in determining an appropriate balance between public benefit of neural interface devices and public risk. See discussion in chapter 4 under the heading '(b) Policy Considerations'.

[736] The analysis on manufacturer liability in chapter 5 determined that neural interface devices must comply with six Essential Principles and nine other Essential Principles regarding design and construction, which apply to devices on a case-by-case analysis, all of which are specified in Schedule 1, Part 1 and Part 2 *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth), respectively.

[737] Arkin, Ulam and Duncan, above n 667, 163-5.

[738] Carroll, above n 10, 80. The method of machine governance incorporating similar steps that could be adapted for neural interface devices was discussed in chapter 5; Arkin, above n 667, 8.

[739] See analysis in chapter 5 under the heading '*2* Neural Interface Device Beyond Being a Tool'.

[740] See chapter 1 under the heading '*2* The Chosen Theory for Hypothesis Determination'.

apply established principles[741] in legal actions. As anomalous results occur,[742] the application of the current legislation or common law principles require re-evaluation and adaptation, which incorporates past decisions together with the anomalous results. This will enable the courts to better resolve civil liability proceedings that involve a party with a neural interface device.[743]

The possibility of anomalous results have been illustrated throughout the thesis in relation to the application of the current law in resolving a civil action,[744] most prominently in negligence. Legal experts in the Delphi Method research identified a need for the current law to change and the analysis in chapter 4 highlighted difficulties in the determination of the standard of care that will be applied to a person with a neural interface device[745] and challenges with causation.[746] Recommendations have been made in this chapter to assist with the transition towards a modification of the current law to better resolve difficulties in the application of the current law. The need for adaptation of the current law was also highlighted in the Delphi Method research by the participants who considered how the existing law would resolve the legal issues they had identified in relation to neural interface devices. Approximately half of the participants in the Delphi Method research stated that application of the current legal principles would be adequate while the other half of the participants stated that the current law would need to change to better resolve the legal issues arising.[747]

The integration of the neural interface device with the human mind creates a situation that goes beyond simple tool use which requires the law to consider a new and complex individual. It is not uncommon for there to be opposing views regarding the application of the law to a factual situation and this provides a foundation for the adversarial legal system that exists in Australia. Analysis throughout the thesis supports the conclusion that there is the potential for inconsistent application of the current law arising from the use of neural interface devices and this will result in uncertainty. Ultimately, the legislature or the High

[741] That is, common law principles or legislation such as Civil Liability Legislation.

[742] For example, decisions that go beyond the existing law, as was discussed in relation to *Donoghue v Stevenson* [1932] AC 562 in chapter 1.

[743] Kuhn, above n 2.

[744] For example, chapter 4 under the heading '*F* Summary'.

[745] See analysis in chapter 4 under the heading '*1* Standard of Care'.

[746] See analysis in chapter 4 under the heading '*D* Causation'.

[747] See chapter 3 under the headings '*1* The Current Law' and '*2* Development of Current Law'.

Court of Australia, as the final appellate court in Australia, will determine the resolution of this uncertainty.[748] This change in the current law will be primarily in the negligence cause of action where the standard of care to be applied to the person with a neural interface device will need to be considered carefully to ensure the most appropriate standard of care is applied in these new circumstances. The current law in relation to causation in the negligence element of damage will most likely be challenged also. The re-evaluation or adaptation of the current law to better resolve disputes where a party has a neural interface device will occur over time.

The re-evaluation or adaptation of the law is not a paradigm shift but the acceptance of such a change is similar and is captured by Kuhn who stated:

> This is not to suggest that new paradigms triumph ultimately through some mystical aesthetic. On the contrary, very few men desert a tradition for these reasons alone. Often those who do turn out to have been misled. But if a paradigm is ever to triumph it must gain some first supporters, men who will develop it to the point where hardheaded arguments can be produced and multiplied. And even those arguments, when they come, are not individually decisive. Because scientists are reasonable men, one or another argument will ultimately persuade many of them. But there is no single argument that can or should persuade them all. Rather than a single group conversion, what occurs is an increasing shift in the distribution of professional allegiances.[749]
>
> At the start a new candidate for paradigm may have few supporters, and on occasions the supporters' motives may be suspect. Nevertheless, if they are competent, they will improve it, explore its possibilities, and show what it would be like to belong to the community guided by it. And as that goes on, if the paradigm is one destined to win its fight, the number and strength of the persuasive arguments in its favour will increase. More scientists will then be converted, and the exploration of the new paradigm will go on. Gradually the number of experiments, instruments, articles, and books based upon the paradigm will multiply. Still more men, convinced of the new view's fruitfulness, will adopt the new mode of practicing normal science, until at last only a few elderly hold-outs remain. And even they, we cannot say, are wrong. Though the historian can always find men—Priestley, for instance—who were unreasonable to resist for as long as they did, he will not find a point at which resistance becomes illogical or

[748] *Judiciary Act 1903* (Cth) s 35A Criteria for granting special leave to appeal.

[749] Kuhn, above n 2, 158.

unscientific. At most he may wish to say that the man who continues to resist after his whole profession has been converted has *ipso facto* ceased to be a scientist.[750]

G *Further Research Opportunities*

Beyond the resolution of civil liability disputes, chapter 1 identified some of the many legal issues that arise with neural interface devices but are beyond the scope of this thesis. These issues include wireless interception and unauthorised communication with the neural interface device that may be a factor the court will consider should this be alleged by the defendant. Access and use of data collected and stored by the neural interface system may give rise to an action for breach of privacy legislation or breaches of contractual obligations in relation to data protection.[751] The requirement for an individual with a neural interface device to obtain compulsory third party insurance is also a matter that will need to be determined by the legislature and if such insurance is compulsory, this may impact on the decisions of the court as it did in *Imbree*.[752]

Amendment of existing legislation or enactment of new legislation may be necessary to address these issues and to better resolve disputes. While the legislature should consider the regulatory issues that could arise from the use of neural interface devices, legislative intervention was discouraged by the participants in the Delphi Method research examined in chapter 3,[753] as this could inhibit the development and supply of neural interface devices. Further research could be undertaken to determine whether or not the legislature should introduce or amend legislation in relation to neural interface devices and if so, how and when. Legislation might be necessary only if there are insurmountable gaps in the common law so government could pursue a light touch regulatory approach. In chapter 4, it was determined that strict liability is unlikely to be applied to a person with a neural interface device unless it is in unison with compulsory third party liability insurance, as is the case with motor vehicles.[754]

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[750] Ibid 159.

[751] See discussion under the heading '*4* Data Protection/Privacy'.

[752] (2008) 236 CLR 510. See discussion in chapter 1 under the heading '*2* Compulsory Third Party Insurance'.

[753] See chapter 3 under the heading '*2* Development of Current Law'.

[754] See chapter 4 under the heading '*4* Whether the Inference of Negligence (res ipsa loquitur) Applies' and *Imbree v McNeilly* (2008) 236 CLR 510, [129], [130], [180] and [181] (Kirby J).

In the same way that chapter 1 identified issues beyond the scope of this thesis, the following discussion of neuroethics, neurolaw and neuroscientific evidence identifies other research opportunities beyond the scope of this thesis. This discussion is important because it highlights the enormity of issues that will arise with the use of neural interface devices and challenges to the current legislation, common law and beyond. This thesis seeks to provide a contribution to knowledge in the field of neural interface devices and promote further discussion and analysis.

1 *Neuroethics*

Ethical challenges exist and more will arise as neural interface devices become readily available and their capabilities increase. Neuroethics should be considered by researchers, manufacturers, government and the legal professionals as it provides a framework within which civil legal issues, such as those discussed below, could arise. Clausen believes that 'brain–machine interfaces promise therapeutic benefit and should be pursued.'[755] While Clausen admits that these new technologies may pose ethical challenges, he believes that 'these are conceptually similar to those that bioethicists have addressed for other realms of therapy. Ethics is well prepared to deal with the questions in parallel to, and in cooperation with, the neuroscientific research.'[756] Ienca argues that neural interface devices are of particular importance to neuroethics 'as their capacity to establish a direct connection pathway between human neural processing and artificial computation has been described as "qualitatively different" by experts, hence believed to raise "unique concerns".'[757] Ienca recognises privacy risks that 'neurorights', which are composed of a right to mental privacy, psychological continuity and cognitive liberty, could address.[758]

Kevin Warwick considers the issues that might arise in the future relating to intelligent robots and human/machine mergers, known as cyborgs, by identifying science fiction movies such as The Terminator, The Matrix, Blade Runner and I, Robot.[759] Warwick believes that

[755] Clausen, above n 4, 1080.

[756] Ibid.

[757] Ienca, above n 106. See also Rafael Yuste et al, 'Four ethical priorities for neurotechnologies and AI', (2017) 551(7679) *Nature News* 159, 161; Jens Clausen et al, 'Help, hope, and hype: Ethical dimensions of neuroprosthetics' (2017) 356(6345) *Science* 1338, 1338.

[758] Ienca, above n 106.

[759] Kevin Warwick, 'Future Issues with Robots and Cyborgs' (2010) 4(3) *Studies in Ethics, Law, and Technology* Article 6.

scientific developments are raising issues that were not only contemplated in science fiction but go far beyond these.[760] Discussing four different experiments, Warwick identifies particular issues. The use of Radio Frequency Identification Device (RFID) implants to convey our personal identity raises ethical issues when used by children, the aged or prisoners.[761] As robots with biological brains, possibly developed using human neurons, continue to be pursed in research, a range of social and ethical questions will arise, including the extent to which such a cyborg will be entitled to human rights.[762] With greater use of brain-computer interfaces, issues such as mental side effects and liability for unlawful actions of the human recipient exist and the debate over therapy versus enhancement also arises.[763]

However, Ruth Chadwick questions whether the issues raised by Warwick are new questions or only old questions in a new guise.[764] Chadwick focuses on the issues of enhancement involving human thought transfer termed synthetic telepathy, a mechanism that transfers motor cortex instructions to an artificial device and informed consent for deep brain stimulation and brain-machine interface. In relation to enhancement, Chadwick stresses the need to distinguish between 'enhancement' (capabilities that humans do not have) and 'improvement' and concludes that despite the fact that the ability to transfer human thought is an enhancement, criteria are required, possibly moral judgement, to determine whether or not it is an improvement.[765]

Where there has been a device developed to assist humans with a particular ailment, such as deafness, the community for which the device has been created might resist use of the device. Some within the deaf community regard the cochlear implant 'as an enhancement beyond normal functioning'.[766] 'What is enhancement and what is treatment depends on defining normality and disease, and this is notoriously difficult.'[767] Anita Silvers has described the use of prostheses such as corrective lenses, artificial limbs and hearing aids

[760] Ibid.

[761] Ibid.

[762] Ibid.

[763] Ibid.

[764] Ruth Chadwick, 'New Questions, or Only Old Questions in a New Guise' (2010) 4(3) *Studies in Ethics, Law, and Technology* Article 8.

[765] Ibid.

[766] Clausen, above n 4, 1080.

[767] Ibid.

as a ‘tyranny of the normal’ designed to alter a person’s level of functioning to a normal mode of functioning which compromises, rather than equalises, their opportunities.[768]

Chadwick considered brain-machine interface used for deep brain stimulation, drawing analogies with mind-altering drugs and transplantation of neural tissue.[769] The core issue, according to Chadwick, appears to be ‘the description of the machine’s job as ”out think the human brain”.’[770] This conflicts with the evolving area of cognitive computing discussed in chapter 2.[771] However, Chadwick argues that drugs and neural tissue transplants do not operate in this way, they are not innately intelligent.[772] ‘The fact that an intelligent machine is preventing my brain from doing what it ”wants” to do is something I may accept because my natural brain is not doing what ”I” want it to do’. [773] This threat to the “I”, states Chadwick, ‘is certainly not a new philosophical puzzle’.[774] Complications in legal responsibility, such as alteration of personality including mood, memory function and speech control, might arise where the machine changes the brain.[775] However, ‘side effects are common in most medical interventions’, Clausen argues, so ‘this does not illustrate a new ethical problem’.[776] That is, of course, based on what is regarded as the appropriate motivation for obtaining such change.

For these reasons, researchers proposing to engage in neural interface device research within, or in collaboration with, the higher education sector will need to ensure that the relevant neuroethics issues are being addressed. Researchers should also consider whether or not the release of research outcomes should be avoided or restricted if misappropriation of the research outcomes could pose a serious threat to the public.[777]

Further research could also be undertaken to determine whether or not research funding bodies should consider grant terms that specify the appropriate use of the neuroscientific

[768] Anita Silvers, ‘A Fatal Attraction to Normalizing: Treating Disabilities as Deviations from Species-Typical Functioning’ in E Parens (ed), *Enhancing Human Traits: Ethical and Social Implications*, (Georgetown University Press, USA, 1998) 95, 114.

[769] Chadwick, above n 764.

[770] Ibid.

[771] See analysis under the heading ‘*3* Inaccurate Recording and Decoding of Neural Impulses’.

[772] Ibid.

[773] Ibid 3.

[774] Ibid 4.

[775] Clausen, above n 4.

[776] Ibid.

[777] Lawrence O Gostin, *Global Health Law* (Harvard University Press, 2014) 378-80.

research outcomes and expressly prohibit uses that conflict with established codes or rules, such as the European Parliament *Civil Law Rules on Robotics*.[778] This could include analysis of the impact of increased government funding for organisations that provide 'responsible, ethical and scientifically sound translation of neuroscience into the legal arena,' as is the focus of the work done at the Massachusetts General Hospital Center for Law, Brain, and Behavior.[779]

2 *Neurolaw*

Aligned with neuroethics is the developing field of neurolaw that will also influence the law in its application to neural interface devices.

> Less than three decades ago, the fields of cognitive psychology and neuroscience joined forces to form cognitive neuroscience. More recently, neuroscience has combined with social psychology and with economics to produce social neuroscience and neuroeconomics. Each of these amalgamations has been revolutionary in its own way. Neurolaw extends this trend.[780]

The term 'neurolaw' was first used in 1991 by J. Sherrod Taylor, a lawyer who was describing 'the converging courses of neuropsychology and the legal system'.[781] Erickson argues that the term was 'adopted to explain the growing influence of expert testimony by neuropsychologists in brain-injury civil suits' which resulted in its primary focus being the securing of 'financial remedies for people with traumatic brain injuries'.[782] 'But the allure of neurolaw from its conception was its ability to describe personhood by reference to structural and functional aspects of the brain'.[783] The availability of neuroscientific information on how the human brain operates has increased through the development of technological

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[778] European Parliament, *European Parliament Resolution of 16 February 2017 with Recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL))* (16 February 2017) <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2017-0051+0+DOC+PDF+V0//EN>.

[779] Massachusetts General Hospital, above n 309.

[780] Annabelle Belcher and Water Sinnot-Armstrong, 'Neurolaw' (2010) *WIREs Cognitive Science* 1(1), 18, 18.

[781] Steven K Erickson, 'Blaming the Brain', (2010) 11(1) *Minnesota Journal of Law, Science and Technology* 27, 35. In support of this conclusion, Erickson cites the following article: J. Sherrod Taylor et al., Neuropsychologists and Neurolawyers, (1991) 5 *Neuropsychology* 293, 293. Taylor's collaborators were J. Elliott and J. A. Harp.

[782] Erickson, above n 781, 35.

[783] Ibid.

sophistication[784] and research funding.[785] 'The consequence of this overflow of information means that the nuances of scientific explanations when applied to legal questions are often in tension with the established precedents of legal doctrine'.[786]

Today, neurolaw now involves researchers from the social sciences, mind and brain sciences, law and philosophy examining the social and legal implications of neuroscientific discoveries in addressing legal and social problems.[787] Outcomes and recommendations that have come from this field of research include the unreliability of lie detection tests,[788] 'the potential of direct brain interventions to treat anti-social behaviour instead of punishing criminals'[789] in the traditional ways, the limits of free choice[790] and the ability to predict future criminal behaviour.[791] Neurolaw is developing as a recognised area of legal practice 'as the need for lawyers with specialized knowledge in the field of brain injury has become apparent'.[792] The research that has been undertaken in this thesis will integrate with neurolaw as the discoveries in neuroscience enhance the ability for the neural interface devices to better interpret the neural impulses correctly. Future analysis, discussion and recommendations regarding the challenges to the current law by the development of neural interface devices could be promoted within the field of neurolaw.

3 *Neuroscientific Evidence*

Neuroscientific research outcomes are influencing both the legislature and the judiciary. Justice Bryer of the US Supreme Court stated that cutting-edge neuroscience has shown 'virtual violence in video game playing results in those neural patterns that are considered

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[784] Ibid 35-6.

[785] National Institutes of Health, *BRAIN 2025: A Scientific Vision*, above n 276.

[786] Erickson, above n 781, 35, 36.

[787] The Academy of Social Sciences in Australia, *Neurolaw in Australia Revealing the Hidden Impact of Neuroscience and Behavioural Genetics on Australian Law* (2011) <https://www.assa.edu.au/event/neurolaw-in-australia-revealing-the-hidden-impact-of-neuroscience-and-behavioural-genetics-on-australian-law/>.

[788] The MacArthur Foundation Research Network on Law and Neuroscience, *fMRI and Lie Detection* (2016) <http://lawneuro.org/LieDetect.pdf>.

[789] The Academy of Social Sciences in Australia, above n 787.

[790] David M Eagleman, 'The Brain on Trial' (2011) July/August *The Atlantic* <http://www.theatlantic.com/magazine/archive/2011/07/the-brain-on-trial/8520/>.

[791] Jeffrey Rosen, 'The Brain on the Stand', *The New York Times Magazine* (online), 11 March 2007, 1 <http://www.nytimes.com/2007/03/11/magazine/11Neurolaw.t.html?_r=1>.

[792] Charles G Monnett III, *Neurolaw: The Basics*, HG.org <https://www.hg.org/article.asp?id=7464>.

characteristic for aggressive cognition and behavior'.[793] Neuroscientific evidence will be of great importance in a civil dispute where a party has a neural interface device and the factors that lead to the incident in dispute, including communication between the brain and the decoder, must be determined.

A number of cases reinforce the admissibility of evidence comprising of CT scans and diagnostic MRI scans require expert witnesses to provide the court with assurances of the reliability of the evidence in supporting the conclusions proposed by the parties. The factual basis upon which expert opinion is admissible has been established in the Australian courts for these types of neuroscientific evidence.[794] New forms of neuroscientific evidence, including functional magnetic resonance imaging (fMRI) scans, Electroencephalography (EEG), quantitative EEG (QEEG), single-photon emission computed tomography (SPECT) and positron emission tomography (PET) scans, must achieve such recognition otherwise the court will declare it inadmissible. These new forms of evidence may have profound impact on aspects of the litigious process, such as factual causation examined in chapter 4.[795]

The introduction of new forms of neuroscientific evidence may encounter similar rejection as was the case in *R v Tang*[796] in relation to facial and body mapping[797] but the role of expert witnesses in being able to provide reassurance to the court on the validity of conclusions drawn from the evidence will be paramount. However, the way in which these conclusions are communicated to the court must be considered carefully to ensure legal reliability.

Owen Jones believes that 'There are two primary ways that neuroscience can be relevant to law: 1) it can pose new problems; and 2) it can offer aid in solving existing problems.'[798]

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[793] *Brown v Entertainment Merchants Association* 564 U.S. 08-1448 (27 June 2011), 13.

[794] For example, *R v Jeong Ming Foo* [2008] NSWSC 587; *R v KT* [2007] NSWSC 83; *Tabet v Gett* [2010] HCA 12; *Burgess v Leech* [2007] NSWSC 700; and *R v Coleman* [2010] 9 NSWSC 177.

[795] See analysis under the heading '*1* Factual Causation'.

[796] (2006) 65 NSWLR 681.

[797] "Facial mapping" is concerned with identification of a person in a visually captured image (in this case a videotape) on the basis of facial characteristics. "Body mapping" is concerned with the identification of a person in a visually captured image (in this case a videotape) on the basis of physical characteristics of other parts of their body and of posture.

[798] Owen Jones, 'Seven ways neuroscience aids law' in A Battro, S Dehaene, and W Singer (eds), *Neurosciences and the human person: new perspectives on human activities* (2013) Pontifical Academy of Sciences, Vatican City, *Scripta Varia* 121, 124.

Jones has suggested seven general functions which neuroscientific data might serve in litigation, including:

- To provide buttressing for other evidence. That is, 'neuroscientific evidence collaterally supports, and further strengthens, something that already stands independently (or nearly so)'.[799]
- To identify and combat bias.
- To detect the existence of a legally relevant fact (such as the existence of pain or of an addiction).
- To assist in determining the likelihood of future behaviour.[800]

In *Clinton Tuite v The Queen*,[801] the issue that the Victorian Court of Appeal was to determine was the reliability of DNA evidence which utilises a relatively new statistical methodology.[802] The Court applied *R v Tang*[803] in relation to determining the admissibility of the evidence[804] and then considered the evidentiary reliability. Citing the Supreme Court of Canada, the Court said that:

> The dangers of "junk science" are obvious, as that Court had pointed out: Dressed up in scientific language which the jury does not easily understand and submitted through a witness of impressive antecedents, this evidence is apt to be accepted by the jury as being virtually infallible and as having more weight than it deserves.[805]

In the view of the Victorian Court of Appeal, 'the touchstone of reliability for scientific evidence must be trustworthiness, and trustworthiness depends on validation. We would respectfully adopt what the US Supreme Court said in *Daubert*, as follows':[806]

> We note that scientists typically distinguish between "validity" (does the principle support what it purports to show?) and "reliability" (does application of the principle produce

[799] Ibid.
[800] Ibid 124-8.
[801] [2015] VSCA 148.
[802] *Clinton Tuite v The Queen* [2015] VSCA 148, [1].
[803] (2006) 65 NSWLR 681.
[804] *Clinton Tuite v R* [2015] VSCA 148, [58].
[805] Ibid [89]. The Supreme Court of Canada judgment cited was *R v Mohan* [1994] 2 SCR 9, 21.
[806] *Clinton Tuite v The Queen* [2015] VSCA 148, [101].

> consistent results?). Although "the difference between accuracy, validity, and reliability may be such that each is distinct from the other by no more than a hen's kick," ... our reference here is to *evidentiary* reliability -- that is, trustworthiness. In a case involving scientific evidence, *evidentiary reliability will be based upon scientific validity*.[807]

Buckholtz and Faigman assert that if scientifically valid conclusions cannot be drawn from the neuroscientific evidence, then the evidence should not be considered by the law because 'it gives the false appearance of rigor and certainty.'[808] They call for the 'development of a neuro-legal *lingua franca*' to enable the law to align with science by ensuring that the standards applied by the law are based on meaningful, scientific criteria.[809] This will ensure that legal principles involving the 'human mind and mental function' will be grounded in quantifiable and testable concepts of mind and brain,'[810] providing expert witnesses with improved credibility in the courtroom. Research undertaken by Ware, Jones and Schweitzer, revealed that 'the mere presence of neuroscientific information can have an unduly influential effect on decision-makers.'[811]

As new forms of neuroscientific evidence reach the courts, the established evidentiary procedure will work to ensure the careful consideration of these conclusions in combination with the observations of behaviour.[812] Maxwell ACJ, Redlich and Weinberg JJA have expressed this clearly:

> The obvious risk in a criminal trial when expert evidence is led from a forensic scientist is that a jury will give the evidence more weight than it deserves. To prevent unfair prejudice of that kind, it is essential that the reliability of expert evidence be established to the court's satisfaction (under s 137)[813] before it is led. We have concluded that the touchstone of

[807] *Daubert v Merrell Dow Pharmaceuticals Inc* (1993) 509 US 579, 590 n 9 (emphasis added).

[808] Joshua W Buckholtz and David L Faigman, 'Promises, promises for neuroscience and law' (2014) 24(18) *Current Biology*, R861, R866; Jennifer Kulynych, 'Psychiatric neuroimaging evidence: a high-tech crystal ball?' (1997) 49 *Stanford Law Review*, 1249, 1251.

[809] Ibid.

[810] Ibid.

[811] Jillian Ware, Jessica Jones and NJ Schweitzer, 'Neuroimagery and the Jury', (20 August 2014) *The Jury Expert*, 2 <http://www.thejuryexpert.com/2014/08/neuroimagery-and-the-jury/>.

[812] Owen Jones, Anthony Wagner, David Faigman and Marcus Raichle, 'Neuroscientists in Court' (2014) 14 *Nature Reviews: Neuroscience* 730, 731 and 735.

[813] *Evidence Act 2008* (Vic).

> reliability for this purpose is proof of appropriate validation, both of the underlying science (where necessary) and of the particular methodology being employed.[814]

It is clear that the legal reliability of neuroscientific evidence must be based upon scientific validity. Also, recognising that terms in law differ from those in science,[815] further research could be undertaken to assess the feasibility of developing a neuro-legal *lingua franca* to enable the law to align with science, removing ambiguity and uncertainty.

H *Conclusion*

The development of neuroprosthetics enabling the human mind to instruct and control these neural interface devices is occurring. This melding of mind and machine challenges the law in determining where civil liability for injury, damage or loss should lie. This provided an exciting opportunity for legal research and analysis to facilitate the re-evaluation of the applicable law. It has been shown that the extent to which technological advancement in neural interface devices will impact on the law will be substantial. The ability for the law to address this currently unique situation will have a fundamental impact on the parties involved and society at large. The central theme of this thesis was that when a person who has a neural interface device is involved in circumstances where harm to another person or another person's property occurs, the Australian law will require re-evaluation and adaptation to resolve subsequent civil action.

The laws addressing negligence and manufacturer liability are well entrenched in the existing legal systems. Approximately half of the participants in the Delphi Method research undertaken for this thesis and discussed in chapter 3 stated that the current legal framework will be sufficient for resolving the legal issues identified by participants.[816] However, the other half of the participants stated otherwise, that the legal principles will need to change to more adequately resolve the legal issues.[817] Therefore, the certainty of dispute resolution through the direct application of existing law in circumstances where a party has a neural interface

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[814] *Clinton Tuite v The Queen* [2015] VSCA 148, [11]. Footnote 6 in the judgment is the following: *Murphy v R* (1989) 167 CLR 94, 130-1; *R v Mohan* [1994] 2 SCR 9, 21; *Hannes v DPP (Cth)* (2006) 165 A Crim R 151, 226 [289]-[290].

[815] David Hodgson, 'Neuroscience and Criminal Responsibility' (Paper presented at the National Judicial College of Australia, Conference on the Australian Justice System in 2020, Sydney, 25 October 2008) 10.

[816] See analysis under the heading '*1* The Current Law'.

[817] See analysis under the heading '*2* Development of Current Law'.

device is not absolute. Recommendations in this chapter will assist in resolving the challenges of neural interface devices on the common law and legislation to support the use of these innovative devices.

In conclusion, these highly sophisticated, technically advanced and promising capabilities in neural interface devices are an exciting evolution of human development. Legislation and the common law must play an integral role in ensuring the safety of both consumers and the public while enabling individuals with neural interface devices to move freely in Australia without legal constraints beyond those of individuals without neural interface devices. For a quadriplegic person to don an exoskeleton and move through the world as they had before their injury, provides both the developers and the recipients hope and encouragement. Legislation and the common law should not restrict such development and freedom of movement. The quality of life for individuals who require the neural interface devices will be enhanced. Forethought by the judiciary, legal practitioners and the legislature should enable a legal framework that will support and encourage the development of these devices for the good of society.

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VIII APPENDICES

Appendix A Ethics Approval of Delphi Method Research

Ethics Approval

Graeme Orr <g.orr@law.uq.edu.au>

Mon 28/07/2014 11:55 AM

To:Scott Kiel-Chisholm <s.kielchisholm@qut.edu.au>;

Cc:j.bell@law.uq.edu.au <j.bell@law.uq.edu.au>; h.douglas@law.uq.edu.au <h.douglas@law.uq.edu.au>; a.davidson@law.uq.edu.au <a.davidson@law.uq.edu.au>;

Dear Scott (cc Alan as supervisor)

The Law School Research Ethics sub-committee has considered your 3 applications, and is happy to approve the first or 'pre-test' application as low-risk.

We can also conditionally approve the pilot and final surveys as low-risk.
But since a purpose of the pre-test is to help develop the pilot, and the pilot to develop the final survey, *the condition is that you submit an amended application in either case if the nature of those exercises (eg groups surveyed, conditions or nature of survey) were to change materially.*
You can liaise with me at the time if you are unsure if a change were potentially material.

Our only comment is that a typical Delphi survey is done anonymously since the idea is to map common/shared expert conceptions and ideas, which would not need attribution.
But your project is somewhat blue-sky so there may be novel insights gleaned from individual participants, or insights those participants think are novel.
Given the sensitivity of the academic ethic of attributing/crediting others' ideas, and that you are interviewing other academics amongst others, we commend your indication that you will offer attribution to those who wish it. That is something you and your supervisors can give thought to both as you compile the responses and when the time comes for writing up and publication.

regards

Graeme Orr
Professor UQ Law
07 3365 3014
g.orr@law.uq.edu.au
for the Law School Research Ethics Sub-Committee

Appendix B Ethics Approval of Meeting with DEKA Research and Development Executives

Scott Kiel-Chisholm

From:	Graeme Orr <g.orr@law.uq.edu.au>
Sent:	Wednesday, 6 August 2014 12:27 PM
To:	Scott Kiel-Chisholm
Cc:	h.douglas@law.uq.edu.au; j.bell@law.uq.edu.au; a.davidson@law.uq.edu.au
Subject:	RE: Another Ethical Clearance Application

Dear Scott

The law school ethics committee is happy to approve this application, for discussions with DEKA Research and Development Corporation, as low-risk.

It actually generated a debate about what is 'de minimis'.
Researchers often email people in business or academia for comments and information, and it is usually left to the normal protocols.
Prof Douglas did note that in case you acquire information that's not in the public domain (eg has some commercial sensitivity), you were erring on the safe side to send this application.

As a principle, any structured discussion (face to face or not) with a non-academic ,that is likely or directed to gleaning facts or opinions which are not already in the public domain, where the researcher may later wish to include/cite, will ordinary require an application.
Anything else: you don't need to apply for ethical clearance, just apply the normal protocols of getting consent if/when you happen to wish to quote and acknowledging sources/avoiding plagiarism

Graeme Orr
UQ Law 07 3365 3014
g.orr@law.uq.edu.au

Appendix 2.1 A Segment of a Decoding Model Employed in a Neural Interface Device.[818]

C. Decoding Model

Let $\mathbf{z}_k$ be an $N \times 1$ vector of the firing rates of N units measured at discrete time index k, $\mathbf{x}_k$ be a 2-D cursor velocity vector at k, and γ_k be a binary random variable representing whether the cursor was in a click or movement state (i.e., $\gamma_k \in \{\gamma^{(0)}, \gamma^{(1)}\} \equiv \{\text{click}, \text{movement}\}$). The firing rate of each unit was represented by the number of spikes within a non-overlapping time window (100 ms). From the firing rates of N units over L time windows, we created a vector $Z_k = [\mathbf{z}_k^T, \mathbf{z}_{k-1}^T, \ldots, \mathbf{z}_{k-L-1}^T]^T$ that was a $(N \cdot L) \times 1$ short-time history vector of the firing rates. We empirically selected $L = 5$ (i.e., 0.5 s) which we found provided reasonable discrete-state classification performance.

To decode a discrete state, we first represented the *a posteriori* probability of γ_k conditioned on the history of the firing rates Z_k and the previous discrete state γ_{k-1} as in [24]

$$p\left(\gamma_k = \gamma^{(c)} \middle| Z_k\right) = \frac{p\left(\gamma_k = \gamma^{(c)}\right) G(\mathbf{w}^T Z_k; \mu_c \sigma_c)}{\sum_c p\left(\gamma_k = \gamma^{(c)}\right) G(\mathbf{w}^T Z_k; \mu_c \sigma_c)}, \quad c \in \{0, 1\}. \quad (1)$$

$G(\alpha; \beta, \sigma)$ here denotes a univariate Gaussian distribution of a random variable α with a mean β and a standard deviation σ. The vector of weights, $\mathbf{w}$, was used to project Z_k onto a 1-D feature space. The parameters μ_c and σ_c are the mean and standard deviation of the Gaussian probability density function (pdf) of a 1-D variable ($= \mathbf{w}^T Z_k$) in the feature space for class c.

The output from the FD analysis was multiplied by the probability, $p(\gamma_k | \gamma_{k-1})$ that described the probability of discrete state transitions from time $k-1$ to k, which was empirically estimated from the training data. Finally, the state at k was decoded as "click" if

$$\frac{p\left(\gamma_k = \gamma^{(0)} \middle| Z_k, \gamma_{k-1}\right)}{p\left(\gamma_k = \gamma^{(1)} \middle| Z_k, \gamma_{k-1}\right)} > t \quad (2)$$

or "movement" otherwise, where $0 < t < \infty$ was the decision threshold. The threshold t was set to 1 in our study by assuming that each state was likely to occur with the same probability. We observed that overall the posterior probability ratio in (2) was well below 1 for the movement state and well above 1 for the click state. It is possible that optimizing this threshold could improve discrete-state decoding accuracy.

[818] Kim et al, above n 177, 196.

Appendix 3.1: The Pre-test Amendments to the Draft Delphi Method Research Stimulus

Note: This document contains tracked changes to identify the amendments made to the draft Delphi Method research stimulus as a result of conducting the Pre-test.

Legal Issues in the Civil Liability of Neural Interface Devices

The ~~Question~~Research Issue

This study is concerned with how the law will resolve the civil liability issues that will arise with the interaction of neural interface devices with the human mind.

Background

Neuroscience researchers are close to the realisation of devices, commonly termed neural interface devices that will allow both people with no disability or infirmity as well as those who have a disability to control electro-mechanical devices, such as a prostheses or other devices, purely through thinking. Neural interface devices include neuroprosthetics, which are artificial extensions to the body that restore or supplement function of the nervous system lost due to disease or injury. ~~The combination of neural interface device and neuroprosthetic device can be considered a neural interface system.~~

~~For example, a~~A neural interface device could, theoretically, allow a person without an arm to control a prosthetic arm through thinking, rather than through the movement of muscles as is currently the case. It is not beyond the realms of possibility that in the near future a person disabled through a spinal cord injury could drive a car by thinking about steering, accelerating or braking, as distinct from physically controlling the car through neuro-muscular activity.

What are these neural interface devices? Neural interface devices involve a device that enables the sensing of brain signals which are interpreted by a signal processor which then instructs another device, such as prosthetic limb, to effect a specific action. Neural interface devices are systems operating at the intersection of the nervous system (the brain, spinal cord and nerves connecting to every other part of the body) and an internal or external device.

Neural Interface Devices NOT Considered in This Research

Neural interface devices that receive neural impulses and act but do not communicate directly back to the human brain are not the type of device this research is considering. For example, the car that is controlled by the human mind, as discussed above, would not be included if communication occurs in one direction only, that is, from the brain to the car, only. The operation of the car would be identical to a regular car except that commands are given to the car by neural impulse instead of arms and legs. The driver relies solely on their eyes and ears to determine the instructions it gives to the car. There is no communication from the car directly to the brain.

The Specific Type of Neural Interface Device for This Research

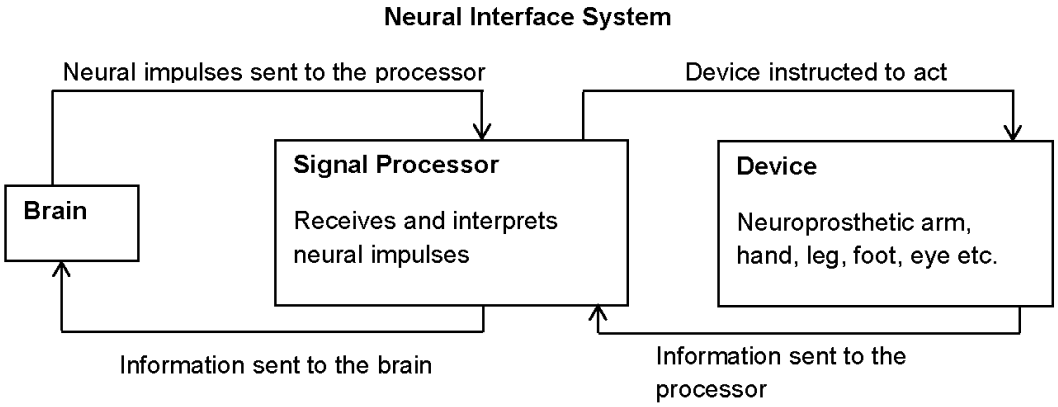
The common characteristics of every neural interface device of interest in this research are their ability to:

1. Sense neural impulses from the brain;
2. Interpret the neural impulses through the use of a signal processor;
3. Communicate with (that is, send signals to) the brain; and
4. Instruct a device to effect a specific action.

The common process that occurs with these types of neural interface devices includes:

1. Neural impulse sent from the brain to the signal processor;
2. Signal processor interprets the bodily action intended by the neural impulse;
3. The signal processor instructs the neuroprosthetic limb or body part;
4. The neuroprosthetic limb or body part sends 'sensory' information back to the neural processor;
5. The neural processor forwards that information on to the brain; and
6. The brain receives the information and determines what further instructions should be sent to the signal processor and on to the neuroprosthetic limb or body part.

This is shown diagrammatically below:



The type of neural interface device of interest in this study must have the feature that the prosthetic device being controlled can communicate directly back to the brain through the neural interface device. For example, a normal person 'knows' about the location and movement in an arm or a leg by direct feedback from the arm or the leg, via the nervous system, to the brain. If you close your eyes you know where your arm is and what it is doing. Similarly, for a disabled person, the neural interface device will communicate directly back to the brain as to the conditions and location of the prosthetic device.

2

The car that is controlled by the human mind, as stated above, or any other neural interface device to be considered in this study, must have the capacity to communicate with the human mind, not through the eyes or other senses but directly with the mind. That is not to disregard the fact that the eyes and ears will be involved in decisions affecting the operation of the device but, just as the biological leg presses down on the car's acceleration pedal, it does not require any other sense to determine the pressure to be applied. The biological leg, with the foot, communicates directly with the brain to operate the accelerator. Once the required speed is achieved, and this is confirmed by the eyes, the pressure applied to the accelerator is adjusted by the leg. The ability for the neural interface device to communicate directly with the human mind, just as the biological limb does, makes the neural interface device analogous to a part of the human body. This is different from a device that can interpret neural impulses and then act, but does not provide feedback to the human mind.

Likewise, while a person with a neural interface device reaching for a grape will be assisted by the eyes, the pressure applied on the grape is not governed by the eyes but by the communication from the device to the mind and back again, just as is the process with the biological limb.

Operation of These Devices is Similar to the Biological Body Part

The initial stimulus that prompts the brain to direct the device to act can come from external or internal origins. For example, a person with neuroprosthetic arm may turn towards the sun and raise their neuroprosthetic hand to reduce the glare as a result of this stimuli –this is an external stimuli. Alternatively a person with the same device might feel like eating a grape - an internal stimuli – and reach with their neuroprosthetic arm for a grape on a table. However, the origin of the stimulus is no different from that experienced by anyone so, for the purposes of this research, is not a focus of the analysis of the workings of the neural interface device.

What is of importance is the process that occurs between the brain, the signal processor and the device. For example, the person wants to pick up a grape so neural impulses move from the brain to the signal processor. The signal processor interprets what the brain wants to happen and then sends instructions to the neuroprosthetic arm. A neuroprosthetic arm is a series of devices that substitute the abilities and sensory functionality of the missing biological arm.

The arm moves towards the grape and as the neuroprosthetic fingers and thumb close in on the grape, signals are sent back to the signal processor notifying it of the pressure being applied to the grape. The signal processor sends impulses back to the brain which acknowledges what the fingers are "feeling" and, via the signal processor, the brain tells the fingers and thumb when to stop closing in on the grape, ensuring the grape does not get squashed.

Likewise, a person with one neuroprosthetic leg wants to run and kick a soccer ball. To begin with, the brain sends neural impulses to the signal processor which interprets what the brain is wanting to happen and then sends instructions to the neuroprosthetic leg and foot. As these move, information is sent back to the signal process that, in turn, sends impulses to the brain. Neural impulses from the brain and information from the neuroprosthetic leg and

foot flow in and out of the signal processor. In unison with the biological leg, the neuroprosthetic leg and foot move to connect with the soccer ball.

Examples of Circumstances Where Civil Liability Might Arise

This study concerns the civil liability of persons with neural interface devices that allegedly cause property damage or personal injury to another. Following are three examples of everyday situations that do not cover every circumstance but provide assistance in imagining when civil liability might arise. The circumstances you might consider are not to be limited by these examples.

First, a disabled person with a neuroprosthetic arm controlled by a neural interface device is carrying a box of books. The person sees a friend who is waving at them. Using the neuroprosthetic arm, the person waves back causing the box of books to fall, hitting another person nearby who falls, breaking a leg.

Second, a person with a neuroprosthetic leg controlled by a neural interface device, riding a conventional ride-on lawn mower, is cutting their neighbour's grass. The neuroprosthetic leg is being used to control the braking of the mower. The neighbour's expensive dog runs out to greet the person and is run over by the lawn mower and is killed. The disabled person claims that they wanted to brake to avoid the dog but could not respond fast enough.

Third, through the use of wireless technology, a disabled person with a neural interface device enables a robot to move towards a cabinet in a store to pick up a highly valuable antique china plate and bring it to another person. Neural impulses move from the person to the robot and information moves from the robot to the person's brain via the neural interface device. This interplay of communication enables the person to "feel" what the robot is touching which enables the person to control the pressure the robot applies to the plate. Being careful not to apply too much pressure on the plate, the person enables the robot to pick up the antique plate and bring it to the person but, due to insufficient pressure, the plate falls to the ground and breaks.

While the scenarios upon which civil liability can arise are infinite, it is the identification of the general legal issues that arise in determining liability that are the focus of this study.

Device Malfunction is Not to be Considered in This Research

Currently, signal processors are unable to interpret neural impulses with 100 per cent accuracy. This is the sole operational limitation of the device with which we are concerned. No other malfunction, in either hardware or software, is to be considered. The steps a person takes to enable them to operate the neural interface device proficiently may be considered. These might include training in the use of the device, learning the abilities and limitations of the device and modifying the way they must think to enable the appropriate action by the device.

The Research Issue

You are asked to consider the civil liability of the person with, and the manufacturer of, the neural interface device only. Consider civil liability to include all grounds for recovery of loss for property damage and personal injury other than criminal. Do not consider any other third party, such as the medical specialists who facilitated the incorporation of the device with the

person. It is to be assumed that the neural interface system is working according to the manufacturer's specifications. The facts of every case will be different so the focus of the study is on the impact of the process of mind, signal processor and device on the law when attributing civil liability for damage to property or person caused by a person using a neural interface system.

Put another way, what are the legal implications of an electrical device moderating the movements and actions of a person?

Legal Issues in the Civil Liability of Neural Interface Devices

The Research Issue

This study is concerned with how the law will resolve the civil liability issues that will arise with the interaction of neural interface devices with the human mind.

Background

Neuroscience researchers are close to the realisation of devices, commonly termed neural interface devices that will allow both people with no disability or infirmity as well as those who have a disability to control electro-mechanical devices, such as a prostheses or other devices, purely through thinking. Neural interface devices include neuroprosthetics, which are artificial extensions to the body that restore or supplement function of the nervous system lost due to disease or injury. Neural interface devices involve a device that enables the sensing of brain signals which are interpreted by a signal processor which then instructs another device, such as prosthetic limb, to effect a specific action. A neural interface device could, theoretically, allow a person without an arm to control a prosthetic arm through thinking, rather than through the movement of muscles as is currently the case.

Neural Interface Devices NOT Considered in This Research

Neural interface devices that receive neural impulses and act but do not communicate directly back to the human brain are not the type of device this research is considering. For example, a car that is controlled by the human mind would **not** be included if communication occurs in one direction only, that is, only from the brain to the car. In this situation there is no communication from the car directly to the brain.

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2. Interpret the neural impulses through the use of a signal processor;
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4. Instruct a device to effect a specific action.

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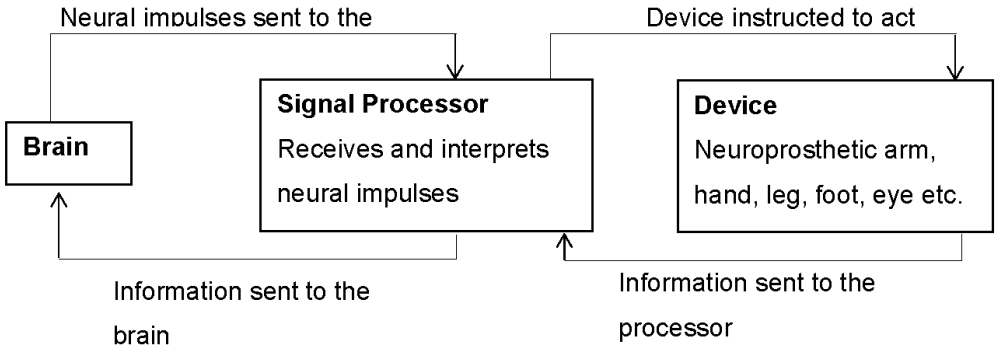
1. Neural impulse sent from the brain to the signal processor;
2. Signal processor interprets the bodily action intended by the neural impulse;
3. The signal processor instructs the neuroprosthetic limb or body part;
4. The neuroprosthetic limb or body part sends 'sensory' information back to the neural processor;
5. The neural processor forwards that information on to the brain; and
6. The brain receives the information and determines what further instructions should be sent to the signal processor and on to the neuroprosthetic limb or body part.

This is shown diagrammatically below:

Neural Interface System



The type of neural interface device of interest in this study must have the feature that the prosthetic device being controlled can communicate directly back to the brain through the neural interface device. For example, a normal person 'knows' about the location and movement in an arm or a leg by direct feedback from the arm or the leg, via the nervous system, to the brain. If you close your eyes you know where your arm is and what it is doing. Similarly, for a disabled person, the neural interface device will communicate directly back to the brain as to the conditions and location of the prosthetic device.

The car that is controlled by the human mind, as stated above, or any other neural interface device to be considered in this study, must have the capacity to communicate with the human mind, not through the eyes or other senses but directly with the mind. That is not to disregard the fact that the eyes and ears will be involved in decisions affecting the operation of the device but, just as the biological leg presses down on the car's acceleration pedal, it does not require any other sense to determine the pressure to be applied. The biological leg, with the foot, communicates directly with the brain to operate the accelerator. Once the required speed is achieved, and this is confirmed by the eyes, the pressure applied to the accelerator is adjusted by the leg. The ability for the neural interface device to communicate directly with the human mind, just as the biological limb does, makes the neural interface device analogous to a part of the human body. This is different from a device that can interpret neural impulses and then act, but does not provide feedback to the human mind.

Likewise, while a person with a neural interface device reaching for a grape will be assisted by the eyes, the pressure applied on the grape is not governed by the eyes but by the communication from the device to the mind and back again, just as is the process with the biological limb.

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What is of importance is the process that occurs between the brain, the signal processor and the device. For example, the person wants to pick up a grape so neural impulses move from the brain to the signal processor. The signal processor interprets what the brain wants to happen and then sends instructions to the neuroprosthetic arm. A neuroprosthetic arm is a series of devices that substitute the abilities and sensory functionality of the missing biological arm.

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Likewise, a person with one neuroprosthetic leg wants to run and kick a soccer ball. To begin with, the brain sends neural impulses to the signal processor which interprets what the brain is wanting to happen and then sends instructions to the neuroprosthetic leg and foot. As these move, information is sent back to the signal processor that, in turn, sends impulses to the brain. Neural impulses from the brain and information from the neuroprosthetic leg and foot flow in and out of the signal processor. In unison with the biological leg, the neuroprosthetic leg and foot move to connect with the soccer ball.

Examples of Circumstances Where Civil Liability Might Arise

This study concerns the civil liability of persons with neural interface devices that allegedly cause property damage or personal injury to another. Following are three examples of everyday situations that provide assistance in imagining when civil liability might arise. The circumstances you might consider are not to be limited by these examples.

First, a disabled person with a neuroprosthetic arm controlled by a neural interface device is carrying a box of books. The person sees a friend who is waving at them. Using the neuroprosthetic arm, the person waves back causing the box of books to fall, hitting another person nearby who falls, breaking a leg.

Second, a person with a neuroprosthetic leg controlled by a neural interface device, riding a conventional ride-on lawn mower, is cutting their neighbour's grass. The neuroprosthetic leg is being used to control the braking of the mower. The neighbour's expensive dog runs out to greet the person and is run over by the lawn mower and is killed. The disabled person claims that they wanted to brake to avoid the dog but could not respond fast enough.

Third, through the use of wireless technology, a disabled person with a neural interface device enables a robot to move towards a cabinet in a store to pick up a highly valuable antique china plate and bring it to another person. Neural impulses move from the person to the robot and information moves from the robot to the person's brain via the neural interface device. This interplay of communication enables the person to "feel" what the robot is touching which enables the person to control the pressure the robot applies to the plate. Being careful not to apply too much pressure on the plate, the person enables the robot to pick up the antique plate and bring it to the person but, due to insufficient pressure, the plate falls to the ground and breaks.

While the scenarios upon which civil liability can arise are infinite, it is the identification of the general legal issues that arise in determining liability that are the focus of this study.

Device Malfunction is Not to be Considered in This Research

Currently, signal processors are unable to interpret neural impulses with 100 per cent accuracy. This is the sole operational limitation of the device with which we are concerned. No other malfunction, in either hardware or software, is to be considered. The steps a person takes to enable them to operate the neural interface device proficiently may be considered. These might include training in the use of the device, learning the abilities and limitations of the device and modifying the way they must think to enable the appropriate action by the device.

The Research Issue

You are asked to consider the civil liability of the person with, and the manufacturer of, the neural interface device only. Consider civil liability to include all grounds for recovery of loss for property damage and personal injury other than criminal. Do not consider any other third party, such as the medical specialists who facilitated the incorporation of the device with the person. It is to be assumed that the neural interface system is working according to the manufacturer's specifications. The facts of every case will be different so the focus of the study is on the impact of the process of mind, signal processor and device on the law when attributing civil liability for damage to property or person caused by a person using a neural interface system.

Put another way, what are the legal implications of an electrical device moderating the movements and actions of a person?

Appendix 3.3 Forms for the Pre-Test

(The Pre-Test is identified in the documents as Study 1)

Participant Information Sheet

Investigator: Scott Kiel-Chisholm, PhD Candidate at The University of Queensland.

Supervisors: Dr Alan Davidson and Professor John Devereux at The University of Queensland.

Project title: Delphi Research Study 1 - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

Objectives: The research survey information interview will enable the researcher to identify any misinterpretation or misunderstanding of the factual basis upon which future participants will answer the survey questions.

To preserve anonymity, you will be allocated an identification code. The meeting will be at a location you specify where you will be provided with a document that has information on the PhD research being undertaken. This information provides the basis upon which an online survey is to be conducted at a future date. You will have the opportunity to read that information and then will be interviewed to ascertain your understanding of the information you have read. Your responses to those questions will enable identification of any problems with the information, such as ambiguity, and this will enable refinement of the information prior to developing and conducting the online survey.

The interview will be recorded to enable accurate capture of your comments but you will not be attributed to any of those comments in any report that may be compiled. In this way your anonymity will be preserved. It is anticipated that the interview will take approximately twenty minutes to conduct.

You are under no obligation to participate, may withdraw at any time and can direct that any information you have provided is to be disregarded and discarded.

If you participate in this study, the information will not be linked back to you as an individual. The information will be stored in a secure environment and access to the data will be made available only to the members of the research team. Your comments will be kept confidential and any information provided will only be used for the purposes of this research.

You are welcome to discuss your participation in this study with the Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], or to impose conditions, or withdraw from the study at any time.

If you would like to speak to an officer of the University not involved in this study, you may contact the University's Ethics Officer on 336 53924.

Participant Consent Form

Dear Participant

Re: Delphi Research Study 1 - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

As a participant in this research, your acceptance is required as confirmation of your informed consent to participating in this interview. By participating in this interview, you agree that you have read and understood the "Participant Information Sheet" for this research project. You agree to participate in this investigation through this interview and understand that you may withdraw at any time. You are free not to answer any of the questions if you choose to do so.

You and your position will **not** be identified in the project. Potential identifying information will be used ONLY for the purpose of providing the researcher with a summary of results.

This study adheres to the Guidelines of the ethical review process of The University of Queensland. Whilst you are free to discuss your participation in this study with the Principal Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], if you would like to speak to an officer of the University not involved in the study, you may contact the University's Ethics Officer on 336 53924.

……

Participant's name

……

Participant's signature

……

Date

Appendix 3.4 Forms for the Pilot of the Delphi Method Research

Participant Consent Form

Dear Participant

Re: Delphi Research Pilot - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

As a participant in this research, your acceptance is required as confirmation of your informed consent to participating in this interview. By participating in this interview, you agree that you have read and understood the "Participant Information Sheet" for this research project. You agree to participate in this investigation through this online research pilot and interview and understand that you may withdraw at any time. You are free not to answer any of the questions if you choose to do so.

You and your position will **not** be identified in the project. Potential identifying information will be used ONLY for the purpose of providing the researcher with a summary of results.

This study adheres to the Guidelines of the ethical review process of The University of Queensland. Whilst you are free to discuss your participation in this study with the Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], if you would like to speak to an officer of the University not involved in the study, you may contact the University's Ethics Officer on 336 53924.

……

Participant's name

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Participant's signature

……

Date

Participant Information Sheet

Investigator: Scott Kiel-Chisholm, PhD Candidate at The University of Queensland.

Supervisors: Dr Alan Davidson and Professor John Devereux at The University of Queensland.

Project title: Delphi Research Pilot - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

Objectives: The pilot will enable the researcher to identify any misinterpretation or misunderstanding of the research information and questions and any operational inaccuracies of the online instrument in capturing the participants' responses. This will enhance the accuracy and credibility of the research results.

To preserve anonymity, you will be allocated an identification code. The completion of the online research and subsequent meeting will be at a location you specify where you will be provided with a document that has information on the PhD research being undertaken. This information provides the basis upon which an online research instrument is to be conducted at a future date. You will have the opportunity to read the online information, complete the online instrument and then will be interviewed to ascertain your feedback on the instrument. Your responses to those interview questions will enable identification of any problems with the information, the questions and the functionality of the instrument. This will enable refinement of the information, questions and instrument functionality prior to conducting the online research.

Notes will be taken during the interview but you will not be attributed to any of those comments in any report that may be compiled. In this way your anonymity will be preserved. It is anticipated that the pilot and interview will take approximately 30 minutes to conduct.

You are under no obligation to participate, may withdraw at any time and can direct that any information you have provided is to be disregarded and discarded.

If you participate in this study, the information will not be linked back to you as an individual. The information will be stored in a secure environment and access to the data will be made available only to the members of the research team. Any information provided will only be used for the purposes of this research.

You are welcome to discuss your participation in this study with the Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], or to impose conditions, or withdraw from the study at any time.

If you would like to speak to an officer of the University not involved in this study, you may contact the University's Ethics Officer on 336 53924.

Appendix 3.5 Forms for Rounds 1 and 2 of the Delphi Method Research

Dear Participant

Re: Delphi Research - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

As a participant in this research, your acceptance is required as confirmation of your informed consent to participating in this online research instrument. By participating in this Delphi Research, you agree that you have read and understood the "Participant Information Sheet" for this research project. You agree to participate in this investigation through this research and understand that you may withdraw at any time. You are free not to answer any of the questions if you choose to do so.

You and your position will **not** be identified in the project without your consent. Potential identifying information will be used ONLY for the purpose of providing the researcher with a summary of results.

This study adheres to the Guidelines of the ethical review process of The University of Queensland. Whilst you are free to discuss your participation in this study with the Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], if you would like to speak to an officer of the University not involved in the study, you may contact the University's Ethics Officer on (07) 3365 3924.

……

Participant's name

……

Participant's signature

……

Date

Investigator: Scott Kiel-Chisholm, PhD Candidate at The University of Queensland.

Supervisors: Dr Alan Davidson and Professor John Devereux at The University of Queensland.

Project title: Delphi Research - Civil Liability Challenges for Neural Interface Devices: Reconceptualising the Law

Objectives: You have agreed to participate in some pioneering research, together with other experts from the judiciary, legal profession and academia. This study is concerned with how the law will resolve the civil liability issues that will arise with the interaction of neural interface devices with the human mind. Your involvement will enable the identification of legal issues that might arise when a person with a neural interface device is a defendant in a civil action.

This will be achieved through:

I. Identification and description of legal issues;

II. Ranking the issues in order of importance;

III. Reasons for the ranking; and

IV. Discussion on steps required to address each issue.

There will be two rounds of this Delphi Research. In the first round you will have the opportunity to identify and discuss the legal issues and the steps the law might take to resolve these issues. In the second round of the study, you will be provided with some of the unidentifiable comments by other participants and statistical information based on responses in the first round of the research. You will have the opportunity to rank the issues in order of importance will also be provided with an opportunity to reconsider the information you provided in the first round and can change your first round responses.

Participation is solely online and it is anticipated that the first round will take you approximately 15 to 20 minutes to conduct and the second round 10 to 15 minutes. To preserve anonymity, you will be allocated an identification code.

You are under no obligation to participate, may withdraw at any time and can direct that any information you have provided is to be disregarded and discarded.

If you participate in this study, the information will only be linked back to you for the purposes of your participation in round 2, but otherwise will not be linked back to you as an individual. The information will be stored in a secure environment and access to the data will be made available only to the members of the research team. Your comments will be kept confidential and any information provided will only be used for the purposes of this research.

You are welcome to discuss your participation in this study with the Investigator, Scott Kiel-Chisholm [phone number and email address] or Principal Supervisor, Dr Alan Davidson [phone number and email address] or Associate Supervisor, Professor John Devereux [phone number and email address], or to impose conditions, or withdraw from the study at any time.

If you would like to speak to an officer of the University not involved in this study, you may contact the University's Ethics Officer on 336 53924.

Appendix 3.6 Summary of Round 1 Legal Issues for Round 2 Delphi Method Research Instrument

In what ways do you consider that these neural interface devices may lead to civil liability?

- Primarily claims for breach of duty of care as a consequence of a failure to take reasonable steps to avoid foreseeable risk.
- A lesser issue may be in connection with strict liability offences such as traffic offences.
- The user may be able to take action against the manufacturer or supplier of the device if it does not operate to the standard that has been promised or is defective.
- A third party may have a cause of action against the user and the manufacturer or supplier if they suffer harm due to the defective operation of the device.
- If the person attempts an act that is beyond the limitations of the device and is aware of this.
- Civil liability will, it seems to me, mostly arise in the context of negligence. the considerations will focus more on the concepts of reasonable foreseeability and the objective 'reasonableness' of the defendants' actions. If, therefore, the potential 'failure' of the device to respond 'perfectly' is foreseeable to a reasonable person fitted with such a device, then it would seem that the user would be liable for any damage caused by that device's failure to perform in the desired way, as they should have taken this potential imperfect response into account when they undertook the action which resulted in the loss and potential liability.
- In relation to civil liability to third parties, if there is forseeability of the risk of harm then there is the potential for civil liability should that harm eventuate. For example, if the user of the device is aware of the limits of their control of the device, or if they engage in activities without giving consideration to any limitations to their control of the device, then they could be held liabile for any damage caused by their failure to control the device. An analogy is that a person who drives a car, knowing that they have a medical condition which may affect their reflexes from time to time, injures a third party whilst driving, even though the accident is caused by the manifestation of the condition, may still be liable in negligence.

- Liability for the user of the device and for the manufacturer. For example, an injured plaintiff may sue both the person with the device who injured them and the manufacturer of the device. Even if only the user is sued by the plaintiff, the user may cross-claim against the manufacturer.
- There may also be situations where the user is the injured person but the defendant alleges contributory negligence against the user (i.e. the limitations of the device meant the user was not taking sufficient care for themselves by doing whatever they did).
- The device may itself injure the user, giving rise to an action by the user against the manufacturer.

What legal issues will arise through the use of such devices?

- Civil claims in connection with breach of duty of care made against both user and manufacturer of device, civil penalties against user of device including in relation to traffic offences.
- Assuming approval by relevant government bodies, TGA etc, there may be exposure for government also.
- As with the use of any other mechanical device operated by a person that results in injury to others, the courts will need to determine whether that damage has been caused by the negligence of the user or some defect in the device. If it is the latter, could that defect have been avoided by the user (e.g.through proper maintenance) or should the liability fall upon the manufacturer or supplier of the product.
- Questions will arise as to whether the user has been properly trained in the use of the device or has sought such training. If the person has been trained, was the provider of that training in some way negligent? What is the nature and extent of any duty of care owed by the trainer to third parties who may be injured as a result of use of the device? The risk of harm is clearly foreseeable if a person is not properly trained and informed about use of the device.
- A further question will be whether the user ought not to have engaged in particular activities until such time as they can be completely confident that they are entirely proficient and also fully aware of the limitations of the device. Their behaviour ought to be consistent with any limitations that arise due to the nature

of the device and its capabilities. If the user has been appropriately trained and adhered to any limitations upon the use of the device, then they should be in no different position to an able-bodied person who causes injury to another. Resolution of the preceding issues may give rise to difficult causation questions. For example, was the dropping of the antique china plate caused by ordinary negligence or was the cause something unique to the use of this device? If the latter, then matters such as training, adherence to restrictions on use and so forth will arise.

- The foreseeability of imperfect (including imprecise) responses by the device would seem to be crucial, as would the need for a user to undertake sufficient training in the use of the device, lest that shortfall in training be in itself regarded as unreasonable and therefore giving rise to potential liability. Questions will therefore arise as to what level of training should be undertaken by potential users of such devices before they would be considered to have taken reasonable precautions to avoid the consequences of imprecise operation of the device. This might well be tempered by 'social utility' arguments, which would propose that the benefit received by the use of the device warrants a level of risk taking that might otherwise be considered unreasonable. It would seem to me therefore than any user of such a device would be well advised to take out insurance to cover the possibility of imperfect performance of the device, as such a precaution might well be considered to be the appropriate (and therefore 'reasonable') response to such potential incidents.
- There may be legal issues concerning the appropriateness of surgery etc.
- The use of such devices would, I think, form part of any negligence action rather than create stand alone issues of and by themselves. So, for example, if there is an accident such as the lawnmower incident the use of the device would go to legal issues such as causation, and defences and assessment of damages.
- Standard of care to be determined in negligence. *Volenti* - would it apply in the person with the device undertakes an activity knowing that there may be limitations/delayed reactions?
- Questions of proportionate liability and contributory negligence. There may also be real questions as to causation if it can be shown the device malfunctioned (i.e. it did not behave in a way which reflected the user's intention e.g. the user

meant the arm to move to the right, but a malfunction meant it moved to the left).

- Every case will turn on its own facts. Foreseeability will be a signficant issue. Factual causation and scope of liabiilty may also be significant. Some defences may be available, such as contributory negligence and the 'obvious risk'; defence under s 5F and 5G CLA. The consumer laws may be relevant to any potential claim against the manufacturer.

What legal principles will be involved?

- In the absence of any special statutory regime, these matters will need to be determined in accordance with the ordinary principles of tort and contract and relevant statutory provisions, e.g. the *Civil Lability Act* and the *Australian Consumer Law*.
- In negligence it will be all elements of the action (and all defences). I think the use of the devices will cross over all elements - which ones are raised in an action will depend upon the facts of the case. It is of course possible that existing principles may be extended to attune to new situations - after all the law does evolve.
- Depends upon the scenario, so usual legal principles would apply.
- The usual principles regarding civil liability for 'negligence' will continue to apply - the balancing of the issues about who should pay when damage is caused by human activity. The common law has a great deal of historical experience in addressing these issues.
- Tort, contract and manufacturers liability.
- The law of negligence as governed by the Civil Liability legislation and the common law. Duty of care, breach, damage and causation will all have to be proven.
- Negligence, Sale of goods and Australian consumer law relating to the supply of goods and/or services.

How will the law resolve these issues?

- It may be useful to consider how courts have treated civil claims and criminal offences where a contributing factor was the disability of the 'perpetrator' or the

views judicial officers have expressed in cases where the ability to 'control' an autonomous person or thing (animal, vehicle etc) was an issue.

- Intention and notions of the human body
- In relation to the user and the manufacturer, rather than third party liability, the consumer legislation may have relevance.
- Fears of potential product liability by the manufacturers would seem to be a very limiting factor in the development, manufacture and distribution of such devices.
- Any necessary maintenance required of the technology to maintain the highest accuracy of the device.

Appendix 3.7 Participant Responses Rounds 1 and 2

1. In what ways do you consider that these neural interface devices may lead to civil liability?

- Primarily claims for breach of duty of care as a consequence of a failure to take reasonable steps to avoid foreseeable risk'.
- A lesser issue may be in connection with strict liability offences such as traffic offences.
- Civil claims in connection with breach of duty of care made against both user and manufacturer of device, civil penalties against user of device including in relation to traffic offences.
- Where the neural interface device allows the person to perform daily common place activities, such as driving a motor vehicle, but the manner of performing the activity by the person then falls short of the standard of care that applies to any person performing that activity.
- The user may be able to take action against the manufacturer or supplier of the device if it does not operate to the standard that has been promised or is defective.
- A third party may have a cause of action against the user and the manufacturer or supplier if they suffer harm due to the defective operation of the device.
- If the person attempts an act that is beyond the limitations of the device and is aware of this.
- Civil liability will, it seems to me, mostly arise in the context of negligence. The considerations will focus more on the concepts of reasonable foreseeability and the objective 'reasonableness' of the defendant's actions. If, therefore, the potential 'failure' of the device to respond 'perfectly' is foreseeable to a reasonable person fitted with such a device, then it would seem that the user would be liable for any damage caused by that device's failure to perform in the desired way, as they should have taken this potential imperfect response into account when they undertook the action which resulted in the loss and potential liability.
- In relation to civil liability to third parties, if there is forseeability of the risk of harm then there is the potential for civil liability should that harm eventuate. For example, if the user of the device is aware of the limits of their control of the device, or if they engage in activities without giving consideration to any

limitations to their control of the device, then they could be held liabile for any damage caused by their failure to control the device. An analogy is that a person who drives a car, knowing that they have a medical condition which may affect their reflexes from time to time, injures a third party whilst driving, even though the accident is caused by the manifestation of the condition, may still be liable in negligence.

- Liability for the user of the device and for the manufacturer. For example, an injured plaintiff may sue both the person with the device who injured them and the manufacturer of the device. Even if only the user is sued by the plaintiff, the user may cross-claim against the manufacturer.
- There may also be situations where the user is the injured person but the defendant alleges contributory negligence against the user (i.e. the limitations of the device meant the user was not taking sufficient care for themselves by doing whatever they did).
- The device may itself injure the user, giving rise to an action by the user against the manufacturer.
- As with the use of any other mechanical device operated by a person that results in injury to others, the courts will need to determine whether that damage has been caused by the negligence of the user or some defect in the device. If it is the latter, could that defect have been avoided by the user (e.g.through proper maintenance) or should the liability fall upon the manufacturer or supplier of the product.
- Questions will arise as to whether the user has been properly trained in the use of the device or has sought such training. If the person has been trained, was the provider of that training in some way negligent? What is the nature and extent of any duty of care owed by the trainer to third parties who may be injured as a result of use of the device? The risk of harm is clearly foreseeable if a person is not properly trained and informed about use of the device.
- A further question will be whether the user ought not to have engaged in particular activities until such time as they can be completely confident that they are entirely proficient and also fully aware of the limitations of the device. Their behaviour ought to be consistent with any limitations that arise due to the nature of the device and its capabilities. If the user has been appropriately trained and

adhered to any limitations upon the use of the device, then they should be in no different position to an able-bodied person who causes injury to another. Resolution of the preceding issues may give rise to difficult causation questions. For example, was the dropping of the antique china plate caused by ordinary negligence or was the cause something unique to the use of this device? If the latter, then matters such as training, adherence to restrictions on use and so forth will arise.

- The foreseeability of imperfect (including imprecise) responses by the device would seem to be crucial, as would the need for a user to undertake sufficient training in the use of the device, lest that shortfall in training be in itself regarded as unreasonable and therefore giving rise to potential liability. Questions will therefore arise as to what level of training should be undertaken by potential users of such devices before they would be considered to have taken reasonable precautions to avoid the consequences of imprecise operation of the device. This might well be tempered by 'social utility' arguments, which would propose that the benefit received by the use of the device warrants a level of risk taking that might otherwise be considered unreasonable. It would seem to me therefore than any user of such a device would be well advised to take out insurance to cover the possibility of imperfect performance of the device, as such a precaution might well be considered to be the appropriate (and therefore 'reasonable') response to such potential incidents.
- There may be legal issues concerning the appropriateness of surgery etc.
- Through their negligent use or manufacture.
- Negligence claims against the user. Perhaps also intentional torts. CCA / ACL claims against manufacturers.
- Poor instructional manuals'. Another respondent said, 'Primarily negligence. Secondarily, product liability provisions.

2. What legal issues will arise through the use of such devices?

- Manufacturer of the neural interface device to indemnify the user of such device for any damage caused by the negligence of the user, as a result of using the device or to those who suffer property damage or personal injury as a result.
- Assuming approval by relevant government bodies, TGA etc, there may be exposure for government also.

- A legal practitioner said, 'Civil claims in connection with breach of duty of care made against both user and manufacturer of device, civil penalties also.
- The use of such devices would, I think, form part of any negligence action rather than create stand alone issues of, and by, themselves. So, for example, if there is an accident such as the lawnmower incident the use of the device would go to legal issues such as causation, defences and assessment of damages.
- Standard of care to be determined in negligence. *Volenti* - would it apply if the person with the device undertakes an activity knowing that there may be limitations/delayed reactions?
- Questions of proportionate liability and contributory negligence. There may also be real questions as to causation if it can be shown the device malfunctioned (i.e. it did not behave in a way which reflected the user's intention e.g. the user meant the arm to move to the right, but a malfunction meant it moved to the left).
- Every case will turn on its own facts. Foreseeability will be a signficant issue. Factual causation and scope of liability may also be significant. Some defences may be available, such as contributory negligence and the 'obvious risk', defence under ss 5F and 5G CLA. The consumer laws may be relevant to any potential claim against the manufacturer.
- Primarily an evaluation of the risk caused by the imperfect translation of the brain's instructions. I analyse it in this way. First, if there were perfect translation of the brain's instructions then one would be analysing the issues of any injury scenario in the usual way: primarily negligence and if there was a prosthetic arm by an examination of whether that made any difference. The only thing changed by the neural interface is the risk of imperfect translation. That won't affect the articulation of the existence of the duty or the identification of the standard of care, it will just affect assessment of risk and manner of causation. And of course, difficulties of proof (because the question of whether, and if so, the degree of imperfect translation will be something entirely within the mind of the defendant).
- It is likely that the principal challenges in negligence claims against users of NIDs will be in relation to establishing the appropriate standard of care and determining breach. Also, the act / omission distinction may be challenging.

Factual challenges will likely arise in causation. In intentional torts, the concepts of 'intentional' and 'act' will be important. In relations to manufacturers, the application of key concepts (such as 'acceptable quality'; 'safety defect' etc) under the CCA / ACL.

- Warranties, optimal use scope of use limits of devices.

3. How will the law resolve these issues?

- The law will resolve these issues by applying the tort principles and those statutory provisions that cover supply of goods and services.
- One missing is misleading and deceptive conduct (representations that device is more effective/safer than it actually is... for example). I would say this could be very important. Also, various other aspect of defence/analysis of defect--adequacy of information provided, failure to warn of risk which materialised.. etc. Again very important.
- I expect that courts will determine civil claims and criminal claims in accordance with established principles and will not seek to devise solutions or exemptions to 'excuse' or mitigate the liability of users and manufacturers. Any solution in the manner of exemptions etc will need to be driven by legislative reform.
- The issues mentioned in response to the previous question can be resolved by application of the ordinary principles of negligence and relevant statutory provisions, e.g. the Competition and Consumer Law. The questions of causation are likely to be difficult. I cannot see any basis to take a special approach to the resolution of these issues. It seems to me that there is a clear analogy with a driver who is blind in one eye or a paraplegic driving a vehicle with modified controls. They will need to adapt their driving practices so as to reduce the risk of causing harm to others. The user of a neural interface device will similarly have to adapt their behaviour so as to avoid causing harm to others.
- Through existing legal principles. Issues of new technology will be subsumed under existing legal categories.
- Apply the law as it currently is. Torts law can easily take this into account.
- Good question. Our common law tradition, particularly in relation to negligence issues, would indicate that a body of relevant law will develop incrementally as the courts consider individual cases as they arise. The insurance issues

mentioned above will probably be crucial to these decisions, as the courts seek to balance the social utility of such devices against the protection of third parties from potential 'malfunctions'. Courts will ask 'who should pay?' for any damage which arises and this will be a difficult decision. I would suggest that the complexities of these questions are such that they would be best left to the common law to resolve, and that interested parties should be very cautious about seeking legislation, as this will 'freeze' the flexible development of appropriate laws.

  - By the application of existing principles. Analogies will be drawn with the application of the law to the operation of cars and other equipment.
  - By applying established principles to the circumstances of each case.
- The application of the usual rules of negligence' while two law academics said, 'Principled and incremental development of existing principles (of the law of negligence and statutory interpretation)' and 'Probably by a step by step and evolving approach.
- I agree that they will be dealt with through orthodox legal principle and applicable statute law.

4. What legal principles will be involved?

- Negligence, sale of goods and Australian Consumer Law relating to the supply of goods and/or services.
- In the absence of any special statutory regime, these matters will need to be determined in accordance with the ordinary principles of tort and contract and relevant statutory provisions, e.g. the *Civil Liability Act* and the *Australian Consumer Law*.
- In negligence it will be all elements of the action (and all defences). I think the use of the devices will cross over all elements - which ones are raised in an action will depend upon the facts of the case. It is of course possible that existing principles may be extended to attune to new situations - after all the law does evolve.
- Depends upon the scenario, so usual legal principles would apply.
- The usual principles regarding civil liability for 'negligence' will continue to apply - the balancing of the issues about who should pay when damage is caused by

human activity. The common law has a great deal of historical experience in addressing these issues.

- Tort, contract and manufacturers liability.
- The law of negligence as governed by the civil liability legislation and the common law. Duty of care, breach, damage and causation will all have to be proven.
- In negligence: 'reasonable person'; standard of care; foreseeability; direct vs indirect harm. In intentional torts: act; intention; direct vs indirect interference and tortious principles'.

5. Is there any other information you would like to have in developing your answers to the legal issues?

- Ultimately, answers to these questions will turn on the extent to which there are factors which 'excuse' or act in mitigation so as to minimise exposure of users and manufacturers to accepted civil and criminal law standards. It may be important to understand the extent to which each category of persons understands the limitations on their ability to control the devices and how to manage risk through avoidance of risky activities etc. also any other ways in which risks can be identified and mitigated.
- Is there previous experience of death or serious injury or significant property damage caused by the lack of accuracy or the signal processor being unable to interpret neural impulses with 100% accuracy? Are there conditions (e.g. extreme temperatures) in which the signal processor will be unlikely to interpret the neural impulses with accuracy and which therefore should be avoided by the user of the neural interface device?' Two other participants provided the following:
- Not really - though the nature, predictability and frequency of these sorts of 'failures', and the general reliability of individual devices outlined in your introductory paper would be central to any such considerations.
- If the extent of risk of imperfect translation is the real issue, then information concerning the way in which the translation works scientifically; then information about evaluating the size of the risk; how that was communicated to the user; and evidence concerning the particular mechanics of what happened on the

day of the incident: to what extent if at all did imperfect translation actually occur and if it did to what extent was it causative.

- Given the technology, I would have thought there might be data available to identify causation with some additional precision than contemplated above--sort of like 'black box data' which could, for example, identify whether the instruction from the brain was turn left but the arm turned right, or not brake (pull instead of push). The availability of something like that would be very helpful in the determination of causation. I think people (decision-makers) would be more likely to 'blame' the device maker than the (sympathetic disabled) person using it -- just human nature. Easier to say it malfunctioned and go for deep pocket. Of course, the factual situation may make this easier or harder.

- Need to consider the regulatory climate, as well.

6. Are there any other legal issues related to the use of these devices which would be of interest?

- It may be useful to consider how courts have treated civil claims and criminal offences where a contributing factor was the disability of the 'perpetrator' or the views judicial officers have expressed in cases where the ability to 'control' an autonomous person or thing (animal, vehicle etc) was an issue.
- Intention and notions of the human body.
- In relation to the user and the manufacturer, rather than third party liability, the consumer legislation may have relevance.
- Fears of potential product liability by the manufacturers would seem to be a very limiting factor in the development, manufacture and distribution of such devices.
- Any necessary maintenance required of the technology to maintain the highest accuracy of the device.

7. Are there any other comments you would like to make?

- These questions require some imagination in making the responses. My thinking at this stage is that the approach to liability will still require some comparison with the usual standard of care expected of any person in the same situation without a neural interface device. I am looking forward to the next round.

- I am not sure the use of such devices will take the law into unchartered waters or require the development of new principles.
- It may be worthwhile researching any decided cases in which negligence has been alleged against persons who have been in control of prostheses or other medical devices. I'm not in a position to do so in the time available. I do think that the High Court, if it was required to look at this issue, would apply established principles to the circumstances of individual cases.
- Any comprehensive consideration of the legal issues which arise would seem to involve an amalgam of laws related, for example, to motor vehicle manufacturers and to those governing the introduction of new drugs. I don't think these legal issues are truly novel, rather they require the application of streams of law which seem to me to be fairly well developed.
- No other than to say this is very interesting.
- A fascinating area of societal and legal development.